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Nicotine Withdrawal: Assessing the FDA's Effort to Regulate Tobacco Products

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NICOTINE WITHDRAWAL: ASSESSING THE FDA'S EFFORT TO REGULATE TOBACCO PRODUCTS

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I. INTRODUCTION

At a press conference held on August 23, 1996, just one year after initially revealing his plans,¹ President Clinton announced sweeping federal regulations to combat the underage use of tobacco products.² The Food and Drug Administration (FDA) subsequently published a lengthy preamble to accompany the final regulations, detailing the Agency's assessment of the problem and responding to numerous public comments to its notice of proposed rulemaking (NPRM).³ Characterizing the growing use of tobacco products as a "pediatric disease," FDA Commissioner David Kessler previously had vowed to alter the smoking habits of the newest generation of tobacco users in order to "radically reduce the incidence of smoking-related death and disease."⁴

The tobacco regulations deal with both cigarettes and smokeless tobacco products, and they focus primarily on the advertising, sale, and distribution of these products to children and adolescents.⁵ Among other things, the regulations establish

1. See Todd S. Purdam, *Teenagers and Tobacco: Clinton Proposes Broad Plan to Curb Teen-Age Smoking*, N.Y. TIMES, Aug. 11, 1995, at A1; see also 60 Fed. Reg. 41,314 (1995) (notice of proposed rulemaking); 60 Fed. Reg. 41,453 (1995) (accompanying jurisdictional statement).

2. See Peter Kilborn, *Clinton Approves a Series of Curbs on Cigarette Ads*, N.Y. TIMES, Aug. 24, 1996, at 1; Claudia MacLachlan, *Tobacco's Road is Smooth: FDA Regs Face Legal Fight*, NAT'L L.J., Sept. 9, 1996, at B1.

3. See 61 Fed. Reg. 44,396, 44,616-18 (1996) (to be codified at 21 C.F.R. pt. 897).

4. Suein L. Hwang et al., *FDA Seeks to Mount Attack on Smoking by Minors That Could Mean Regulation*, WALL ST. J., July 13, 1995, at A3. In the preamble, the FDA cites 1994 figures from the Surgeon General's office indicating that more than three million American adolescents currently smoke cigarettes and that an additional one million adolescent males use smokeless tobacco. See 61 Fed. Reg. at 44,398, 44,421-22. The Centers for Disease Control (CDC) recently released a state-by-state compilation of smoking patterns. The report indicates very high rates of teenage tobacco use in some parts of the United States. See Dana M. Shelton et al., U.S. Department of Health and Human Services, *State Laws on Tobacco Control—United States, 1995*, 44 MORBIDITY & MORTALITY WKLY. REP., No. SS-6, Nov. 3, 1995, at 24-25; see also Barnaby J. Feder, *Increase in Teen-Age Smoking Sharpest Among Black Males*, N.Y. TIMES, May 24, 1996, at A20 (reporting that the CDC's latest survey indicated that almost 35% of persons age 17 and under had admitted smoking in the previous month as compared with 30% just three years earlier).

5. See 61 Fed. Reg. at 44,397-99, 44,422-24. The FDA also published as an

a federal minimum age for the purchase of tobacco products, prohibit some vending machine sales, and limit the format and content of, as well as the conditions under which minors are exposed to, tobacco product advertising.⁶ The Agency also plans to require that the tobacco industry undertake a substantial educational program aimed at minors to provide information about the harmful consequences of using tobacco products and to counteract the appealing images associated with tobacco use in recent advertising campaigns.⁷

In originally announcing these initiatives, President Clinton had invited Congress to intercede with a legislative response.⁸ In fact, Mr. Clinton suggested that Congress would have only ninety days to respond if it wished to prevent finalization of the regulations.⁹ The FDA frequently extends comment periods, however, and it did so in this case.¹⁰ Moreover, before issuing a final rule, an agency must consider and prepare responses to all material comments received.¹¹ For a relatively simple proposal,

"annex" a separate document which more fully set out its legal arguments for asserting jurisdiction over tobacco products. *See* 61 Fed. Reg. 44,619 (1996) (jurisdictional statement); *see also id.* at 45,274 n.1227 (explaining that the Agency employed notice-and-comment rulemaking procedures in formulating its jurisdictional analysis even though not required to do so). It is not clear why the FDA proceeded in this fashion, unless perhaps it thought that a notice asserting its claim for jurisdiction over tobacco products might have some independent significance.

6. *See* 61 Fed. Reg. at 44,396-97 (summarizing the new regulations). Most of the restrictions will take effect after one year, except the age limitation will apply in six months, while the prohibition on brand-name sponsorship will not take effect for two years. *See id.* at 44,542-43 (noting that manufacturers also will have two years to comply with the registration, listing, and good manufacturing practice requirements applicable to all medical devices).

7. *See id.* at 44,538, 44,590.

8. *See Teenagers and Tobacco: Excerpts from Clinton News Conference on His Tobacco Order*, N.Y. TIMES, Aug. 11, 1995, at A18.

9. *See President's Anti-Smoking Initiative Faces Formidable Challenges*, BALTIMORE SUN, Aug. 11, 1995, at 14A (noting that Mr. Clinton urged Congress to use the 90-day comment period to develop compromise legislation).

10. The comment period originally closed on November 9, 1995, but was later extended to January 2, 1996. *See* 60 Fed. Reg. 53,560 (1995). The Agency then briefly reopened the comment period in late March. *See* 61 Fed. Reg. 11,349 (1996); 61 Fed. Reg. 11,419 (1996); Timothy Noah & Suein L. Hwang, *Philip Morris, in Voluminous Comment, Denies Manipulating Cigarette Nicotine*, WALL ST. J., Apr. 23, 1996, at A24.

11. Guarantees of public participation would be meaningless unless agencies honestly considered and responded to significant comments on proposals. *See, e.g., St. James Hosp. v. Heckler*, 760 F.2d 1460, 1470 (7th Cir. 1985); *Home Box Office*,

this process might take weeks or months, while, for more complex and controversial proposals such as the tobacco NPRM, this process might take years to complete;¹² indeed, some proposals are never finalized.¹³

In light of the clearly exaggerated urgency of the matter and the radical nature of the FDA's proposals, some commentators viewed the announcement as no more than a political gesture, a threat made with the hope of forcing Congress' hand.¹⁴ In fact, the FDA previously had asked Congress for guidance on the matter,¹⁵ although that had occurred before the mid-term elections gave the Republican Party a majority in Congress. In the past, Congress has been notoriously hesitant to enact legislation controlling tobacco products,¹⁶ and it did not initially react to the proposals, evidently waiting to see if the FDA's threat of action was serious.¹⁷

The tobacco industry, itself under siege from various fronts

Inc. v. FCC, 567 F.2d 9, 35 (D.C. Cir. 1977).

12. Cf. M. Elizabeth Magill, *Congressional Control Over Agency Rulemaking: The Nutrition Labeling and Education Act's Hammer Provisions*, 50 FOOD & DRUG L.J. 149, 165-70 (1995) (describing the FDA's failure to meet strict congressional deadlines for the issuance of final nutrition labeling regulations).

13. See, e.g., 56 Fed. Reg. 67,440 (1991) (withdrawing 89 FDA proposals, most of which had been pending for more than ten years).

14. See Claudia MacLachlan, *FDA Draws First in Tobacco Wars*, NAT'L L.J., Aug. 28, 1995, at A1, A21.

15. See *Regulation of Tobacco Products (Part I): Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 103d Cong. 33 (1994) (statement of David A. Kessler, Commissioner of Food and Drugs) ("On these issues we seek guidance from the Congress."); Anita Manning, *Smoking Under Fire from the FDA and Others*, USA TODAY, Mar. 29, 1994, at 6D.

16. See Wayne Hearn, *Anti-Smoking Group Gives Government Bad Grades*, AMER. MED. NEWS, Feb. 7, 1994, at 20 (noting that Congress failed to pass almost all of the 1,000 tobacco control bills introduced over a 30-year period); *infra* note 59 (listing several unenacted bills which would have given the FDA regulatory authority over tobacco products).

17. See Barnaby J. Feder, *Big Tobacco Victory Creates Joy and Profit on Wall Street*, N.Y. TIMES, May 24, 1996, at D1, D8 ("[A]nalysts expect Congress, as long as it is Republican-controlled, to deny the [FDA] the funds it would need to follow through."); Timothy Noah, *Smoke Under Fire: Controversy Over Wigand Reflects Broader Government War on Tobacco*, WALL ST. J., Feb. 2, 1996, at A12 ("Republicans . . . are poised to press legislation to block an ambitious [FDA] rule, but are holding back in hopes that a federal judge strikes it down first."). A number of bills were introduced shortly after the FDA announced its proposals. See, e.g., S. 1262, 104th Cong. (1995); S. 1295, 104th Cong. (1995); H.R. 2283, 104th Cong. (1995); H.R. 2414, 104th Cong. (1995).

over the last few years,¹⁸ took the threat seriously, both in filing extensive comments with the FDA¹⁹ and in launching preemptive judicial challenges to the Agency's assertion of jurisdiction.²⁰ For his part, President Clinton capitalized on the under-age use of tobacco as a campaign issue—his Republican challenger, Bob Dole, was sharply criticized for his earlier opposition to the initiative.²¹

Although the broad public health goals underlying the regulations seem unassailable, there are serious doubts about the Agency's assertion of legal authority to regulate tobacco products in the manner selected. The FDA's initiative could still force a rapid legislative response,²² but this depends in part on how

18. See, e.g., Noah, *supra* note 17, at A12 (“[T]he government is waging a war of attrition against the tobacco industry. Taking place at both the federal and state levels, the war also includes a number of private civil actions . . .”). Several states have filed suit against companies to recover costs associated with health care for residents with tobacco-related illnesses. See Jonathan S. Massey, *The Florida Tobacco Liability Law: Fairy Tale Objections to a Reasonable Solution to Florida's Medicaid Crisis*, 46 FLA. L. REV. 591 (1994); Andrew A. Skolnick, *Spate of Lawsuits May Finally Find Chink in Tobacco Industry's "Impenetrable Armor,"* 273 JAMA 1080 (1995).

19. See Noah, *supra* note 17, at A12 (“Currently, the FDA is reviewing 700,000 public comments on the rule, more than the agency has ever received on any single regulation, the majority of them negative.”). On the final day of the comment period, the Tobacco Institute and five of the major cigarette manufacturers filed 2,000 pages of comments and 45,000 pages of footnotes and other documentation arguing against the proposed regulations. See 61 Fed. Reg. 44,396, 44,418 (1996); 61 Fed. Reg. 44,619, 45,272 (1996) (jurisdictional statement); Timothy Noah, *Cigarette Firms Challenge FDA's Right to Restrict Minors' Access to Tobacco*, WALL ST. J., Jan. 2, 1996, at B8.

20. See, e.g., Coyne Beahm, Inc. v. FDA, No. 2:95CV0059 (M.D.N.C. filed Aug. 10, 1995); see also Barnaby J. Feder, *Tobacco Curbs Face Legal Fight*, N.Y. TIMES, Aug. 24, 1996, at 8 (describing the predicted course of pending lawsuits in the wake of the FDA's recent finalization of the regulations). Other questionable FDA decisions often are not formally challenged because a company may fear alienating the Agency. See *Allegations of FDA Abuses of Authority: Hearings Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 104th Cong. (1995).

21. See Judi Hasson, *Debate Centers on Economy, Government Role*, USA TODAY, Oct. 7, 1996, at 12A (“Clinton charged [in the first Presidential debate] that Dole sided with tobacco companies when the administration tried to block cigarette sales and advertising to minors.”); Timothy Noah, *Dole's Remarks on Tobacco Addition Leave Him Open to Savage Criticism*, WALL ST. J., July 5, 1996, at A8; *Dole Opposes FDA's Steps to Regulate Tobacco Items*, WALL ST. J., June 14, 1996, at A16.

22. Under a recently enacted procedure, Congress gets 60 days after the publication of a “major” rule to introduce a joint resolution of disapproval, and then it has 60 session days in which to vote on the resolution under “fast track” procedures (which, among other things, substantially limit the opportunity for amendments and

persuasive one finds the Agency's assertion that it has the legal authority to issue the rules. This Article will critically evaluate claims that the FDA has exceeded statutory and constitutional limitations on its power.

Part II focuses on objections to the Agency's claim that it can regulate the advertising of tobacco products using the special statutory provisions applicable to restricted medical devices. The FDA argues that nicotine qualifies as a drug because tobacco companies intend that consumers become addicted to nicotine containing products. Even if true, the Agency still must justify the assertion of authority over products traditionally regulated by another agency, and then it must explain the counterintuitive classification of tobacco products as medical devices, and also as restricted devices, rather than as drugs.

Part III canvasses some of the apparently unanticipated consequences of this device classification, including the possibility that cigarette manufacturers may enjoy a broader preemption defense in tort lawsuits. Finally, Part IV addresses the relative strength of some of the various constitutional objections raised by the industry, particularly with regard to the advertising restrictions and the proposed industry-financed educational campaign. Ultimately, this Article concludes that the FDA regulations exceed the Agency's delegated authority and that the proposed educational campaign contravenes the First Amendment.

II. STATUTORY OBJECTIONS TO THE REGULATIONS

During the last quarter of a century, the FDA has been notoriously creative in construing its own statutory authority. In the early 1970s, high level Agency officials expressed the view that the Federal Food, Drug and Cosmetic Act (FD&C Act)²³ represents a broad "constitution" authorizing the FDA to protect the public health by any necessary and proper means, rather

filibusters). See Contract With America Advancement Act of 1996, Pub. L. No. 104-121, § 251, 110 Stat. 868 (to be codified at 5 U.S.C. §§ 801-808). The FDA designated its new regulation as a "major" rule subject to this procedure. See 61 Fed. Reg. at 44,615. Of course, the President ultimately would remain free to veto any such resolution of disapproval.

23. Federal Food, Drug and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-395 (1994)).

than a limited and precise delegation of Congress' legislative power.²⁴ Some might applaud the Agency for its adaptability to changing circumstances, but others have credibly accused it of overreaching and arbitrariness.²⁵

Although courts show significant deference to an agency's interpretation of its statutory authority,²⁶ they need not countenance expansive constructions of an agency's regulatory jurisdiction.²⁷ For the most part, the courts have not rebuffed the

24. See Peter Barton Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 28 FOOD DRUG COSM. L.J. 177, 178 (1973) ("[T]he Act must be regarded as a constitution. . . . The mission of the [FDA] is to implement [its fundamental] objectives through the most effective and efficient controls that can be devised."); see also *United States v. Dotterweich*, 320 U.S. 277, 280 (1943) (suggesting that the FD&C Act be treated as "a working instrument of government and not merely as a collection of English words").

25. See, e.g., 62 Cases of *Jam v. United States*, 340 U.S. 593, 600 (1951) ("In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop."); *Southeastern Minerals, Inc. v. Harris*, 622 F.2d 758, 767 (5th Cir. 1980) (criticizing the FDA's "bureaucratic hubris that confuses abuse of power with reason"); *United States v. Parkinson*, 240 F.2d 918, 921 (9th Cir. 1956) ("The record of the past few decades is replete with examples of the tendency of executive agencies to expand their field of operations. A passion and a zeal to crusade affects their operations."); H. Thomas Austern, *Philosophy of Regulation: A Reply to Mr. Hutt*, 28 FOOD DRUG COSM. L.J. 189, 191 (1973) (criticizing the suggestion that "a well-motivated administrative agency can legally do what it alone deems desirable unless Congress has in advance specifically prohibited it"); James D. Poliquin, Comment, *The Incremental Development of an Extra-Statutory System of Regulation: A Critique of Food and Drug Administration Regulation of Added Poisonous and Deleterious Substances*, 33 ME. L. REV. 103, 103 (1981) ("[T]he agency has chosen to take advantage of the statute's ambiguity to enhance its regulatory powers, often assigning strained interpretations of the statute to advance the agency's perceived goals.").

26. See, e.g., *NationsBank of N.C., N.A. v. Variable Annuity Life Ins. Co.*, 115 S. Ct. 810, 813-15 (1995); *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984); see also Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 980-93 (1992); Mark Seidenfeld, *A Syncopated Chevron: Emphasizing Reasoned Decisionmaking in Reviewing Agency Interpretations of Statutes*, 73 TEX. L. REV. 83, 94-103 (1994).

27. See, e.g., *Mississippi Power & Light Co. v. Mississippi ex rel. Moore*, 487 U.S. 354, 386 (1988) (Brennan, J., dissenting) ("Our agency deference cases have always been limited to statutes the agency was 'entrusted to administer.'") (quoting *Chevron*, 467 U.S. at 844); Board of Governors of Fed. Reserve Sys. v. Dimension Fin. Corp., 474 U.S. 361, 368 (1986) (rejecting Federal Reserve's interpretation of its statutory jurisdiction as including institutions offering NOW accounts); see also Abner S. Greene, *Checks and Balances in an Era of Presidential Lawmaking*, 61 U. CHI. L. REV. 123, 185-87 (1994); Cass R. Sunstein, *Law and Administration After Chevron*, 90 COLUM. L. REV. 2071, 2097-2101 (1990).

FDA's self-serving and generous claims of power. In recently promulgating its tobacco regulations, however, the Agency may have crossed the line. In doing so, it has diverted scarce resources and may have unwittingly imperiled its core missions.²⁸

A. *Jurisdiction to Regulate Tobacco Products*

The FDA's jurisdiction to regulate cigarettes and smokeless tobacco products depends on answers to a couple of questions. First, do tobacco products fit within one of the many product categories over which the Agency exercises authority? The FDA contends that nicotine satisfies the definition of the term "drug" because of its addictive effect coupled with evidence of the industry's intent that it affect the structure or function of the body in this manner.²⁹ Second, even if one accepts the FDA's asserted product categorization, did Congress nonetheless mean to reserve jurisdiction over tobacco product labeling and advertising for an agency other than the FDA, namely, the Federal Trade Commission (FTC)? These questions are taken up in turn below.

1. *FDA Authority Over Drugs.*—Under the FD&C Act, a "drug" is any "article[] intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man . . . [or] intended to affect the structure or any function of the body of man."³⁰ The mere presence of a chemically active substance would not satisfy this definition;³¹ the manufacturer must in-

28. See Benjamin Wittes, *Tobacco Lobby Keeps on Smoking*, LEGAL TIMES, Apr. 15, 1996, at 1, 5 (describing tobacco industry's congressional lobbying strategy as emphasizing the FDA's diversion of resources from other important regulatory activities); M-D-D-I REPORTS ("The Gray Sheet"), Jan. 8, 1996, at I&W-3 ("Personnel reassignments to the tobacco initiative have filtered down to the FDA Center level, with the Commissioner's office pulling at least one staff member from each of the agency's centers [P]rogress on farther-term device reg[ulation]s could be slowed by the tobacco effort."); see also 61 Fed. Reg. 44,396, 44,598 (1996) ("FDA projects that between 30 to 50 full-time employees (FTE's) will be needed to implement the rule.").

29. The Agency's collateral argument that tobacco products are "medical devices" under the Act, which is discussed in Part II.B, *infra*, depends entirely on its threshold claim that the nicotine delivered by such products qualifies as a drug.

30. 21 U.S.C. § 321(g)(1)(B), (C) (1994).

31. See *Action on Smoking & Health v. Harris*, 655 F.2d 236, 239-41 (D.C. Cir.

tend that the substance serve a therapeutic purpose or otherwise affect the structure or function of the body.³² Thus, a product's intended use, rather than its formulation, determines whether it is a drug, even when the product is introduced into, or has some chemical effect upon, the body. The intended use of a product typically is determined by its labeling and any other promotional claims.³³

In the past, the FDA has asserted jurisdiction over tobacco products only when they were accompanied by therapeutic claims.³⁴ The Agency also has declined to regulate "smokeless"

1980) (holding that cigarettes are not drugs simply because they affect the structure or function of the body unless they were intended to be used for this purpose). "[C]onsumers must use the product predominantly—and in fact nearly exclusively—with the appropriate intent before the requisite statutory intent can be inferred." *Id.* at 240; *see also* FTC v. Liggett & Myers Tobacco Co., 108 F. Supp. 573, 576-77 (S.D.N.Y. 1952), *aff'd*, 203 F.2d 955 (2d Cir. 1953).

32. The "structure or any function" definitions of drugs and devices apply only to products which literally claim to change the physical structure of the body or to alter one or more of its basic functions. *See* E.R. Squibb & Sons, Inc. v. Bowen, 870 F.2d 678, 682-83 (D.C. Cir. 1989) (noting that "the 'structure or . . . function' definition, unlike the 'disease in man' definition, is relatively narrow, and was not intended to encompass all articles that might have some remote physical effect upon the body"); *United States v. Article . . . "Sudden Change,"* 409 F.2d 734, 741 (2d Cir. 1969) (holding that lotion claiming to create a "face lift" purports to affect the structure or function of the body and is therefore a drug); *United States v. An Article . . . "Line Away,"* 415 F.2d 369, 371-72 (3d Cir. 1969) (same); *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455, 459 (4th Cir. 1960) (holding that surgical nail inserted into broken bone is a "device" within the meaning of the structure or function definition); *United States v. 23, More or Less, Articles*, 192 F.2d 308, 309 (2d Cir. 1951) (holding that phonograph record purporting to induce sleep is a "device" because sleep is a function of the body).

33. *See, e.g., United States v. Article of Drug . . . B-Complex Cholinols Capsules*, 362 F.2d 923, 925-26 (3d Cir. 1966) (radio broadcasts); *Nature Food Centres, Inc. v. United States*, 310 F.2d 67, 70 (1st Cir. 1962) (public lectures); *V.E. Irons, Inc. v. United States*, 244 F.2d 34, 44 (1st Cir. 1957) (oral representations made by authorized sales distributors); *United States v. General Nutrition, Inc.*, 638 F. Supp. 556, 563-64 (W.D.N.Y. 1986) (same); *Hanson v. United States*, 417 F. Supp. 30, 35 (D. Minn.), *aff'd*, 540 F.2d 947 (8th Cir. 1976); *see also* 21 C.F.R. § 201.128 (1996) (defining "intended use").

34. *See United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959) (holding that cigarettes purporting to reduce appetite affect both the structure (body weight) and function (appetite) of the body); *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F. Supp. 336, 337 (D.N.J. 1953) (holding that the FDA could regulate cigarettes as drugs where their labeling clearly suggested that they would reduce the risk of colds and other infections); *see also Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 337-38 (7th Cir. 1983); *Bradley v. United States*, 264 F. 79, 81-82 (5th Cir. 1920); *United States v. An Article of*

cigarettes as drugs. Smokeless cigarettes heat rather than burn tobacco and thus deliver nicotine into the body while substantially reducing the production and inhalation of other toxic substances. After one tobacco company announced the development of such a cigarette in 1987, two interested groups formally requested that the FDA classify the product as an "alternative nicotine delivery product" subject to regulation as a drug.³⁵ Because the company soon withdrew the product from the market due to poor performance, the FDA declared the issue moot and declined to rule on the petitions.³⁶

Although the FDA has rejected previous requests that it regulate all cigarettes as drugs,³⁷ at least absent therapeutic claims, this factual conclusion remains open to revision.³⁸ The

Drug . . . U.S. Fancy Pure Honey, 218 F. Supp. 208, 211 (E.D. Mich. 1963), *aff'd*, 344 F.2d 288 (6th Cir. 1965); S. REP. No. 73-493, at 2-3 (1934) ("The use to which a product is put will determine the category into which it will fall The manufacturer of the article, through his representations in connection with its sale, can determine the use to which an article is to be put.").

35. See PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW* 384 (2d ed. 1991) (describing petitions filed by the American Medical Association and the Coalition on Smoking or Health); see also *Health Consequences of Smoking: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 100th Cong. 163-64 (1988) (statement of Dr. John Slade) (concluding that the smokeless cigarette will be "the most addictive form of nicotine ever devised," will attract novice smokers, and "may promote relapse to active nicotine dependence"); Michael Waldholz & John Helyar, *FDA Feels Heat on Smokeless Cigarette*, WALL ST. J., Oct. 21, 1988, at B1.

36. See HUTT & MERRILL, *supra* note 35, at 384. Recently, R.J. Reynolds began test marketing a new smokeless cigarette, though amid concerns that the FDA might demand pre-market review. See Barnaby J. Feder, *Ready to Test New Cigarette, Maker Fears Tough Rules*, N.Y. TIMES, Apr. 8, 1996, at A13; Suein L. Hwang & Alix M. Freedman, *Smokers May Mistake "Clean" Cigarette for Safe*, WALL ST. J., Apr. 30, 1996, at B1; see also Anthony Flint, *Race Is on to Sell Nicotine Products*, BOSTON GLOBE, July 29, 1996, at B1.

37. See, e.g., *Action on Smoking & Health*, 655 F.2d at 240 (Nicotine stimulates the senses, but it does not affect the structure or any function of the body; although any article which "comes into contact with any of the senses may be said to be an article intended to affect the functions of the body of man," Congress did not intend the definition to be read so broadly.) (quoting *FTC v. Liggett & Myers Tobacco Co.*, 108 F. Supp. 573, 576 (S.D.N.Y. 1952), *aff'd*, 203 F.2d 955 (2d Cir. 1953)) (internal quotation omitted).

38. See *id.* at 242 n.10 ("Nothing in this opinion should suggest that the Administration is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations. . . . [H]owever, it must provide a reasoned explanation for its action."); see also 21 C.F.R. § 10.85(k) (1996); 61 Fed. Reg. 44,619, 45,219-21 (1996)

FDA now believes that it has accumulated sufficient evidence proving that manufacturers intend that cigarettes and other tobacco products be used to affect the structure or function of the body. The Agency takes the position that tobacco products are intended to satisfy the cravings of persons addicted to nicotine.³⁹

In reaching this conclusion, the FDA relies in part on extensive scientific evidence concerning the addictive nature of nicotine. The FDA summarizes the scientific evidence demonstrating the definable chemical effects that nicotine produces in the brain of the user, including physiological dependence.⁴⁰ Further, it describes studies documenting symptoms of smoking addiction such as continued use despite knowledge of harmful consequences, withdrawal symptoms following abstinence, and continued use despite repeated attempts to quit.⁴¹ The Agency concludes that consumers use tobacco products to satisfy addiction, noting that between seventy-five and ninety-five percent of frequent smokers meet the criteria for addiction established by public health organizations.⁴²

Evidence of addictiveness would not, however, itself suffice to support "drug" jurisdiction over tobacco products. In public statements, tobacco industry executives have argued that nicotine simply improves flavor and does not affect the body of the smoker. In a recent congressional hearing, one tobacco industry executive testified that "nicotine contributes to the taste of ciga-

(jurisdictional statement); *Baltimore & A. R.R. v. Washington Metro. Area Transit Comm'n*, 642 F.2d 1365, 1369-70 (D.C. Cir. 1980); *Bentex Pharms., Inc. v. Richardson*, 463 F.2d 363, 368 n.17 (4th Cir. 1972) ("FDA not only has the right but is obligated to change its opinion if it learns its prior position was erroneous."), *rev'd on other grounds*, 412 U.S. 645 (1973); *International Union, United Auto. Aero. & Agric. Implement Workers of America v. NLRB*, 459 F.2d 1329, 1341 (D.C. Cir. 1972); *AMP, Inc. v. Gardner*, 275 F. Supp. 410, 412 n.1 (S.D.N.Y. 1967), *aff'd*, 389 F.2d 825 (2d Cir. 1968); *United States v. 60 28-Capsule Bottles . . . "Unitrol"*, 211 F. Supp. 207, 215 (D.N.J. 1962).

39. See 61 Fed. Reg. at 44,628-30, 45,203-04. According to lawyers representing plaintiffs in class action lawsuits, an FDA finding that cigarettes are addictive might have a dramatic impact on pending claims against tobacco companies. See Milo Geyelin, *Does FDA's Power Extend to Cigarettes?*, WALL ST. J., Aug. 4, 1995, at B7.

40. See 61 Fed. Reg. at 44,698-730.

41. See *id.* at 44,730-39.

42. See *id.* at 44,812-13, 44,831-55. The Agency also notes that consumers use tobacco products in an effort to control their weight. See *id.* at 44,744.

rettes and the pleasures of smoking . . . [but] does not make cigarettes a drug or smoking an addiction."⁴³ The Tobacco Institute also insists that the manufacturing process focuses entirely on improving taste, though recently publicized documents suggest otherwise.⁴⁴

The FDA has obtained volumes of internal industry documents which characterize nicotine as an addictive substance and candidly describe tobacco products as drug delivery devices.⁴⁵ For example, one document bluntly compared nicotine to morphine and cocaine, concluding that "the primary reason" people smoke "is to deliver nicotine into their bodies."⁴⁶ Moreover, recently unearthed evidence suggests that the industry deliberately targets the youth market.⁴⁷

In addition, evidence suggests that cigarette manufacturers deliberately manipulate nicotine levels. The FDA accuses vari-

43. Alix M. Freedman, *Philip Morris Memo Likens Nicotine to Cocaine*, WALL ST. J., Dec. 8, 1995, at B14.

44. See Alix M. Freedman & Suein L. Hwang, *Why Don't Low-Tar Cigarettes Have Lower Nicotine?*, WALL ST. J., July 14, 1995, at B1; see also Milo Geyelin & Alix M. Freedman, *R.J. Reynolds Once Linked the Success of Rival Brand to "Nicotine Kick" Boost*, WALL ST. J., May 23, 1996, at B2.

45. See, e.g., 61 Fed. Reg. at 44,854-912, 45,100-08; *id.* at 44,856 (quoting the following statement by one tobacco industry executive: "Think of the cigarette pack as a storage container for a day's supply of nicotine. . . . Think of the cigarette as a dispenser for a dose unit of nicotine. . . . Think of a puff of smoke as the vehicle of nicotine Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke."); see also Stanton A. Glanz et al., *Looking Through a Keyhole at the Tobacco Industry: The Brown and Williamson Documents*, 274 JAMA 219 (1995); Alix M. Freedman & Suein L. Hwang, *Three Ex-Employees Say Philip Morris Deliberately Controlled Nicotine Levels*, WALL ST. J., Mar. 19, 1996, at B1.

46. See Timothy Noah et al., *Tobacco Industry Lambastes the FDA for Using Too Many Secret Documents*, WALL ST. J., Jan. 3, 1996, at B1, B2. A draft report from Philip Morris frankly acknowledges the drug status of nicotine and discusses in scientific terms nicotine's effects on the brain: "[A] little nicotine seems to stimulate, while a lot sedates a person. A smoker learns to control the delivery of nicotine through the smoking technique to create the desired mood state." Freedman & Hwang, *supra* note 44, at B1. The report also discusses "nicotine delivery products," mentioning cigarettes along with other products whose sole function is to deliver nicotine into the body: "[N]icotine delivery devices range from snuff, chewing tobacco, cigars, pipes and conventional cigarettes to unique smoking articles, chewing gum, patches, aerosol sprays and inhalers." *Id.* at B14.

47. See 61 Fed. Reg. 44,396, 44,480-81 (1996); *Tactics for Getting Kids to Smoke*, TAMPA TRIB., Nov. 10, 1995, at 18; Patricia Worklan, *R.J. Reynolds' Secret Report Targets Young Adult Market*, CHI. TRIB., July 11, 1996, at 19.

ous segments of the tobacco industry of using special processing techniques such as breeding high-nicotine tobacco leaves, purchasing leaves selectively to raise nicotine content, treating cigarettes with chemicals such as ammonia to enhance nicotine absorption, adding nicotine-rich extracts from outside vendors (though not in domestically-marketed products), and altering nicotine levels in reconstituted tobacco.⁴⁸ According to industry journals, a number of companies engage in blending high-nicotine American tobacco leaves with imported tobacco leaves "to offset the dilution impact of bland foreign tobaccos," enabling "manufacturers to attain the appropriate levels of nicotine in the smoke and provide much of the flavor."⁴⁹

Such evidence seriously undercuts the industry's assertion that its sole concern is product flavor. Indeed, many of the "flavors" of tobacco products can be chemically "denicotinized."⁵⁰ Although the industry has claimed that the ratio of nicotine to tar is constant, recent FTC evaluations reveal a higher proportion of nicotine to tar in certain low-tar cigarettes.⁵¹ Nonetheless, the industry argues that the only valid evidence on which the FDA can rely is a company's advertising claims and other representations to the public.⁵² But if the Agency's allegations

48. See 61 Fed. Reg. at 44,915-94, 45,108-28. Evidence also points to genetic-engineering as a means to manipulate tobacco plants' nicotine levels, and to careful selection of high-nicotine leaves and other tobacco plant parts in creating various tobacco blends. See *id.* at 44,937-38; Benjamin Wittes, *The Tobacco Case the FDA Wants to Make*, LEGAL TIMES, Oct. 23, 1995, at 1, 11.

49. See Wittes, *supra* note 48, at 11-12.

50. See 60 Fed. Reg. 41,453, 41,779-84 (1995); Wittes, *supra* note 48, at 12, 14.

51. See Freedman & Hwang, *supra* note 44, at B1. For example, a Marlboro King filter cigarette had a nicotine-to-tar ratio of 0.069 in 1994, while a Marlboro Lights king-sized filter cigarette had a ratio of 0.08, suggesting that the nicotine level was deliberately raised in the "light" version to compensate for nicotine loss in the tar-reduction process. See *id.*

52. See 61 Fed. Reg. at 45,151; see also Susan H. Carchman, *Should the FDA Regulate Nicotine-Containing Cigarettes? Has the Agency Established a Legal Basis and, If Not, Should Congress Grant It?*, 51 FOOD & DRUG L.J. 85, 114-32 (1996); Ann M. Boeckman, Comment, *An Exercise in Administrative Creativity: The FDA's Assertion of Jurisdiction Over Tobacco*, 45 CATH. U. L. REV. 991, 1025-30 (1996). The FDA has, however, successfully relied on numerous other sources to divine intent, see 61 Fed. Reg. at 45,152-70, including submissions to the Securities and Exchange Commission and statements made in a company's patent applications, see HUTT & MERRILL, *supra* note 35, at 386. In searching for evidence that tobacco companies intend their products to affect the structure or function of the body, the FDA relies in part on statements made in one company's patent application for its high-nicotine

of industry manipulation of nicotine in tobacco products prove supportable, then it may have acquired the previously elusive evidence of an intended drug use.

2. *FTC Authority Over Tobacco Products.*—Although nicotine—the “active ingredient” in tobacco products—may now technically be regarded as a drug, the FDA would not be able to assert its authority at this juncture if Congress has suggested that some other agency has exclusive control over cigarettes and smokeless tobacco products. To be sure, twice during the 1950s the FDA successfully pursued enforcement actions against cigarettes promoted for therapeutic uses.⁵³ Subsequently enacted legislation, however, specifically reserved or delegated to the Federal Trade Commission primary control over the advertising of cigarettes and smokeless tobacco products.⁵⁴ Did Congress thereby intend to exempt tobacco products from the FDA’s control? Absent some contrary intent, Congress is presumed to grant primary jurisdiction over a subject only to a single federal agency.⁵⁵

tobacco product. See 61 Fed. Reg. at 44,937, 45,095.

53. See *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959); *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F. Supp. 336, 337 (D.N.J. 1953).

54. See 15 U.S.C. §§ 4402, 4405 (1994) (smokeless tobacco products); cf. *id.* § 1336 (“Nothing in this chapter shall be construed to limit, restrict, expand, or otherwise affect the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of cigarettes.”); *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 37 (D.C. Cir. 1985). The FTC is now considering revamping its cigarette tar and nicotine labeling requirements to reflect more accurately the range of these chemicals in smoke from “light” cigarettes, which can vary according to individual smoking style. See *FTC Considers Tougher Labeling Rules for Cigarette Ads*, ATLANTA J. CONST., Dec. 29, 1995, at 6B. The Commission also is contemplating enforcement actions against tobacco companies if it finds that they are using tar and nicotine ratings in advertisements to mislead consumers.

55. See *American Pharm. Ass’n v. Weinberger*, 377 F. Supp. 824, 830-31 (D.D.C. 1974) (holding that Congress had delegated primary authority over controlled substances to the Drug Enforcement Administration, and therefore invalidating an FDA effort to restrict the distribution of methadone), *aff’d*, 530 F.2d 1054 (D.C. Cir. 1976) (per curiam); *Brown-Forman Distillers Corp. v. Mathews*, 435 F. Supp. 5, 12-17 (W.D. Ky. 1976) (holding that Congress had delegated primary authority over alcoholic beverages to BATF, thereby invalidating an FDA initiative to require ingredient labeling); cf. *Martin v. Occupational Safety & Health Review Comm’n*, 499 U.S. 144, 151-58 (1991) (holding that Congress had delegated interpretive authority to the Secretary of Labor rather than the Commission); *Breitmeyer v. Califano*, 463 F.

Although a number of federal safety statutes expressly exempt tobacco products,⁵⁶ the FD&C Act was never amended to exclude these products from the FDA's jurisdiction.⁵⁷ Nonetheless, the Agency repeatedly has disclaimed any general authority to regulate cigarettes,⁵⁸ and Congress apparently has failed to enact any of the dozens of bills introduced during the last forty years to grant the FDA such jurisdiction.⁵⁹ Thus, Congress has acquiesced in the FDA's longstanding interpretation of its very limited authority over tobacco products under the FD&C Act.⁶⁰

Supp. 810, 816 (E.D. Mich. 1978) (holding that, where the FDA exercises jurisdiction, its regulatory jurisdiction is exclusive). The Agency disagrees with this contention. See 61 Fed. Reg. at 44,408, 44,415 n.31 (attempting to distinguish *Weinberger*); *id.* at 44,547 ("Numerous Federal agencies have overlapping and complementary jurisdiction that arises from their differing missions and expertise.")

56. See, e.g., 15 U.S.C. § 1459(a)(1) (1994) (exempting tobacco products from the Fair Packaging and Labeling Act); 15 U.S.C. § 2052(a)(1)(B) (1994) (exempting tobacco products from coverage under the Consumer Product Safety Act); 15 U.S.C. § 2602(2)(B)(iii) (1994) (exempting tobacco products from the Toxic Substances Control Act); 21 U.S.C. § 802(6) (1994) (exempting tobacco products from the Controlled Substances Act); see also James T. O'Reilly, *A Consistent Ethic of Safety Regulation: The Case for Improving Regulation of Tobacco Products*, 3 ADMIN. L.J. 215 (1989).

57. The Dietary Supplement Health and Education Act of 1994, which amends the FD&C Act, happens to exclude "tobacco" from the new definition of "dietary supplement." Pub. L. No. 103-417, § 3(a), 108 Stat. 4327 (codified at 21 U.S.C. § 321(ff)(1) (1994)).

58. See, e.g., *Rural Development, Agriculture, and Related Agencies Appropriations for 1990 (Part 8): Hearings Before the House Comm. on Appropriations*, 100th Cong. 409 (1989) (testimony of Frank Young, Commissioner of Food and Drugs); *Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce*, 89th Cong. 193 (1965).

59. See, e.g., H.R. 2147, 103d Cong. (1993) (proposing to prohibit discount coupons and free samples of tobacco products; bar tobacco manufacturers from sponsoring cultural, sports, or other public events; require additional health warnings on cigarette packages; and require that all cigarette additives be disclosed and comply with FDA safety standards); S. 2298, 102d Cong. (1992); H.R. 5041, 101st Cong. (1990); S. 769, 101st Cong. (1989); H.R. 3294, 100th Cong. (1987); H.R. 279, 96th Cong. (1979); S. 3317, 95th Cong. (1978); H.R. 2248, 89th Cong. (1965); S. 1682, 88th Cong. (1963); H.R. 11280, 84th Cong. (1956); see also H.R. REP. NO. 98-805, at 12 (1984) ("Federal laws that protect the public from hazardous food, drugs, and consumer products do not apply to cigarettes."); S. REP. NO. 94-251, at 43 (1976) ("[A]ny further regulation in this sensitive and complex area must be reserved for specific Congressional action.")

60. See *Young v. Community Nutrition Inst.*, 476 U.S. 974, 983 (1986) ("This failure to change the scheme under which the FDA operated is significant, for a congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress." (internal quotation

Moreover, Congress has enacted several statutes restricting tobacco product labeling and advertising without ever suggesting any role for the Agency.

In 1964, the Federal Trade Commission promulgated a stringent regulation to control the advertising of tobacco products and to require that cigarette packages and all other tobacco advertising include a warning statement.⁶¹ Within a year, Congress responded by enacting the Federal Cigarette Labeling and Advertising Act.⁶² The Act was more moderate than the FTC's regulation, which it superseded; for example, Congress required that cigarette packages be labeled with a far less ominous statement "Caution: Cigarette Smoking May Be Hazardous to Your Health."⁶³ In its accompanying declaration of purpose, Congress explained that it sought "to establish a comprehensive Federal

marks omitted)); *United States v. Rutherford*, 442 U.S. 544, 554 n.10 (1979) ("[O]nce an agency's statutory construction has been fully brought to the attention of the public and the Congress, and the latter has not sought to alter that interpretation although it has amended the statute in other respects, then presumably the legislative intent has been correctly discerned." (internal quotation marks omitted)); *Flood v. Kuhn*, 407 U.S. 258, 283 (1972) ("Remedial legislation has been introduced repeatedly in Congress but none has ever been enacted. . . . This, obviously, has been deemed to be something other than mere congressional silence and passivity."); cf. WILLIAM N. ESKRIDGE, JR., *DYNAMIC STATUTORY INTERPRETATION* 241-52 (1994) (evaluating rationales for divining intent from legislative inaction). The FDA does not, of course, accept this argument as compelling. See 61 Fed. Reg. 44,619, 45,255-61, 45,267 (1996) (jurisdictional statement).

61. 29 Fed. Reg. 8324, 8325 (1964) (The required warning label would state "that cigarette smoking is dangerous to health and may cause death from cancer and other diseases."); see also 34 Fed. Reg. 7917 (1969) (discussing 1964 regulation); 111 CONG. REC. 13,900, 13,901 (1965) (statement of Sen. Moss) (discussing state initiatives). For a fuller discussion of the health risks associated with smoking and the history of the anti-smoking movement, see Matthew Baldini, Comment, *The Cigarette Battle: Anti-Smoking Proponents Go for the Knockout*, 26 SETON HALL L. REV. 348 (1995).

62. Pub. L. No. 89-92, § 2, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331-1337 (1994)). The Act barred any other statements relating to smoking and health on any cigarette packages. See *id.* § 5(a). Congress determined that warnings were unnecessary in advertising, but it noted that the FTC's authority with respect to false or misleading cigarette advertising was unaffected by the Act. See H.R. REP. NO. 89-449, at 4-5 (1965), reprinted in 1965 U.S.C.C.A.N. 2350, 2353. The FTC retained its limited authority over tobacco advertising, including authority to require tar and nicotine content disclosure, but Congress granted it no additional powers. See 15 U.S.C. §§ 1335a(a), 1336 (1994). The provisions barring the FTC from requiring warnings to accompany cigarette advertising expired on July 1, 1969. See §§ 5(c), 10, 79 Stat. at 283-84.

63. § 4, 79 Stat. at 283.

Program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health," and to avoid impeding commerce "by diverse, nonuniform, and confusing cigarette labeling and advertising regulations."⁶⁴ Although geared primarily toward displacing state regulation,⁶⁵ Congress also apparently intended to confirm limited regulatory authority in a single federal agency.⁶⁶

The original statute made only ambiguous references to the jurisdiction and authority of the FTC and other federal agencies over cigarette advertising. In 1967, the Federal Communications Commission (FCC) responded to a citizen complaint about broadcast cigarette advertising, holding that, under its "fairness doctrine," stations which broadcast cigarette advertising have a duty to inform listeners of the dangers of smoking by airing public service announcements prepared by interested health organizations.⁶⁷ Shortly thereafter, the FCC proposed to ban cigarette advertising from radio and television.⁶⁸ Similarly, in 1969, the FTC reinstated its rulemaking proceedings to require that warnings accompany all cigarette advertising.⁶⁹

Once again Congress stepped in, this time to supplant the FCC's decision⁷⁰ and to prevent both agencies from finalizing

64. 15 U.S.C. § 1331 (1994).

65. See 61 Fed. Reg. 44,396, 44,544, 44,546 (1996); *infra* Part III.B.1.

66. The Act precluded the FTC, the FDA, and the Public Health Service from imposing any additional health warning requirements on the labeling of cigarettes. See H.R. REP. NO. 89-449, at 19-21 (1965), *reprinted in* 1965 U.S.C.C.A.N. 2350, 2365. *But see* § 10, 79 Stat. at 284 (noting that the termination in 1969 of the provisions of the Act affecting advertising regulation "shall not be construed as limiting, expanding, or otherwise affecting the jurisdiction or authority which the Federal Trade Commission or any other Federal agency had prior to the date of the enactment of this Act"); *Banzhaf v. FCC*, 405 F.2d 1082, 1089 (D.C. Cir. 1968) (holding that 1965 cigarette warning statute did not bar the FCC from requiring stations to broadcast anti-smoking messages).

67. See *Television Station WCBS-TV*, 8 F.C.C.2d 381, *aff'd*, 9 F.C.C.2d 921 (1967), *aff'd*, *Banzhaf v. FCC*, 405 F.2d 1082, 1089-90 (D.C. Cir. 1968).

68. See 34 Fed. Reg. 1959 (1969).

69. See 34 Fed. Reg. 7917 (1969) (proposing to require a detailed warning that "cigarette smoking is dangerous to health and may cause death from cancer, coronary heart disease, chronic bronchitis, pulmonary emphysema, and other diseases").

70. See S. REP. NO. 91-566, at 6-7, 12 (1970), *reprinted in* 1970 U.S.C.C.A.N. 2652, 2657-58, 2663. A similar series of events occurred when the Consumer Product Safety Commission (CPSC) denied a petition requesting that it assert jurisdiction over "high tar" cigarettes. A court held that the CPSC did indeed have jurisdiction over these products. See *American Pub. Health Ass'n v. Consumer Prod. Safety*

their proposals.⁷¹ Effective January 1, 1971, Congress prohibited all broadcast advertising of cigarettes.⁷² In addition to its advertising ban, the 1969 Act required the use of a sterner label "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health."⁷³ In 1984, Congress again amended the statute, requiring quarterly rotation of four different, and very specific, warning labels on cigarette packages.⁷⁴ Thus, over the course of the past three decades, Congress has micromanaged the cigarette labeling and advertising issue.

Cigarettes are not the only tobacco products to have received close legislative attention. In 1986, Congress enacted the

Comm'n, [1972-1975 Transfer Binder] Consumer Prod. Safety Guide (CCH) ¶ 75,081 (D.D.C. May 30, 1975), *vacated as moot*, No. 75-1863 (D.C. Cir. June 15, 1976). Congress reacted swiftly by eliminating the Commission's jurisdiction over cigarettes. See Consumer Product Safety Commission Improvements Act, Pub. L. No. 94-284, § 3(c), 90 Stat. 503 (1976) (codified at 15 U.S.C. § 1261(f)(2) (1994)).

71. Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, § 7(b), 84 Stat. 87, 89 ("Except as provided in subsection (a), nothing in this Act shall be construed to limit, restrict, expand, or otherwise affect the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of cigarettes."). Subsection (a) imposed a stay on the FTC rule regarding cigarette advertising until July 1, 1971. Congress appeared reluctant even to endorse the FTC's authority in this area, let alone that of any other agency, adding that "[n]othing in this Act shall be construed to affirm or deny the Federal Trade Commission's holding that it has the authority to issue trade regulation rules or to require an affirmative statement in any cigarette advertisement." *Id.* § 7(c).

72. See *id.* § 6. Although challenged in court, Congress' broadcast ban was upheld. See *Capital Broad. Co. v. Mitchell*, 333 F. Supp. 582 (D.D.C. 1971), *aff'd mem.*, 405 U.S. 1000 (1972). The district court concluded that the First Amendment rights of broadcasters were not impaired under the statute, and that broadcasters had lost only the ability to collect revenues from others for broadcasting their commercial messages. See *id.* at 584 ("Finding nothing in the Act or its legislative history which precludes a broadcast licensee from airing its own point of view on any aspect of the cigarette smoking question, it is clear that petitioners' speech is not at issue."). Because substantial evidence demonstrated that radio and television advertising effectively reached a large audience of young people, the court held that Congress had a rational basis for prohibiting broadcast advertising. See *id.* at 585-86; see also *infra* Part IV (discussing cigarette advertising restrictions under current commercial speech doctrine).

73. § 4, 84 Stat. at 88.

74. See Comprehensive Smoking Education Act, Pub. L. No. 98-474, § 4(c), 98 Stat. 2200, 2203 (1984) (codified at 15 U.S.C. § 1333(a) (1994)). Similar rotating warnings were prescribed for cigarette advertisements and billboards. See *id.* § 4(a)(2), (3). For a fuller discussion of warning requirements for tobacco and other consumer products, see Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" from the "Need to Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293 (1994).

Comprehensive Smokeless Tobacco Health Education Act.⁷⁵ Responding to concerns that the use of chewing tobacco may cause gum disease and mouth cancer,⁷⁶ Congress adopted warning requirements similar to those required for cigarettes.⁷⁷ The FTC was given the responsibility for implementing and enforcing these requirements.⁷⁸ The Act directed the Department of Health and Human Services (HHS) to establish a public education program,⁷⁹ but Congress never provided funding for any efforts to inform consumers about the health hazards associated with smokeless tobacco products.⁸⁰

Other federal agencies may, of course, still deal with certain tobacco-related issues unrelated to warning labels and advertising. For instance, the Bureau of Alcohol, Tobacco and Firearms (BATF) collects excise taxes and regulates product manufacturing.⁸¹ HHS, of which the FDA is a unit, recently promulgated a

75. Pub. L. No. 99-252, 100 Stat. 30 (1986) (codified at 15 U.S.C. §§ 4401-4408 (1994)).

76. See S. REP. NO. 99-209, at 3-4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 9-10 (expressing concern that young people were using smokeless tobacco products with the misimpression that these were safe alternatives to cigarettes).

77. See 15 U.S.C. § 4402(a)(1), (c)(1) (1994). These same warnings must appear in any advertising for smokeless tobacco products, enclosed in a special circle-and-arrow graphic design. *Id.* § 4402(a)(2), (b)(2)(B).

78. See *id.* §§ 4402(b)-(d), 4404-4405. The FTC's implementing regulations appear in 16 C.F.R. § 307 (1996). One aspect of the FTC's original regulations, exempting advertisements appearing on utilitarian items (such as tote bags) from the warning requirements, subsequently was invalidated. See *Public Citizen v. FTC*, 869 F.2d 1541, 1554-57 (D.C. Cir. 1989); see also 61 Fed. Reg. 45,883 (1996) (finalizing revised regulations to replace those invalidated by the court). The FDA explains that its advertising restrictions extend beyond the scope of the FTC's limited authority in this area. See 61 Fed. Reg. 44,396, 44,545 (1996).

79. See 15 U.S.C. § 4401 (1994). A similar provision was added by the 1984 cigarette legislation. See *id.* § 1341(a). Although HHS apparently has not implemented these programs, presumably it would delegate the task to the Public Health Service, which is responsible for other health education programs, rather than to the FDA. See 42 C.F.R. § 51g (1996) (regulating grants for health education risk reduction); see also 39 FEDERAL YELLOW BOOK II-240 (1996) (listing the "Office on Smoking and Health" in HHS's National Center for Chronic Disease Prevention and Health Promotion).

80. Jeffrey Denny, *Snuff's Tough Stuff; How the Smokeless Tobacco Industry Plays Its Deadly Trade*, WASH. POST, May 16, 1993, at C5.

81. See 27 C.F.R. § 270 (1996). BATF "has no authority over the safety and labeling aspects of tobacco products with respect to consumer product safety." Letter from Daniel R. Black, Deputy Assoc. Dir., BATF, to James T. O'Reilly (Oct. 12, 1988), *cited in* O'Reilly, *supra* note 56, at 226 n.48.

rule requiring all states to maintain and enforce laws prohibiting the sale of tobacco products to persons under the age of eighteen as a condition of receiving block grants controlled by the Department.⁸² HHS also must transmit reports to Congress concerning research on the addictiveness of tobacco products and any recommendations for legislative or administrative action.⁸³ Other federal agencies recently have become interested in the regulation of environmental tobacco smoke.⁸⁴

Even so, the history of federal legislation addressing cigarette labeling and advertising suggests a congressional decision against delegating its legislative authority to any federal agency though reserving some of the FTC's existing authority over advertising as applied to tobacco products and directing it to implement the smokeless tobacco controls. The failure to address the FDA's role is notable but hardly surprising given the Agency's own prior view that it lacked anything other than a limited authority to regulate tobacco products under the FD&C Act. Congressional silence undermines rather than buttresses the FDA's current attempt to restrict the advertising and distribution of cigarettes and smokeless tobacco products.

B. Tobacco Products as Medical Devices

Even assuming that the nicotine in tobacco products falls within the FDA's authority over drugs, the treatment of such products as medical devices seems tenuous. The Agency acknowledges that regulating cigarettes and other tobacco prod-

82. See 61 Fed. Reg. 1492 (1996) (to be codified at 45 C.F.R. §§ 96.122-130) (requiring that states engage in random, unannounced inspections of tobacco product vendors and maintain minimum compliance levels in order to continue to receive grants pursuant to 42 U.S.C. § 300x-26 (1994)).

83. See 42 U.S.C. § 290aa-2(b) (1994).

84. In 1994, the Occupational Safety and Health Administration (OSHA) proposed standards for indoor air quality, including the control of environmental tobacco smoke in the workplace. See 59 Fed. Reg. 15,968 (1994) (proposing to ban smoking in all workplaces except for in designated smoking areas vented directly to the outdoors). The Environmental Protection Agency (EPA) also has addressed the issue of passive smoking. See, e.g., 57 Fed. Reg. 27,772 (1992); see also Alan B. Horowitz, *Terminating the "Passive" Paradox: A Proposal for Federal Regulation of Environmental Tobacco Smoke*, 41 AM. U. L. REV. 183, 215-19 (1991) (suggesting that the EPA issue national uniform standards under the Clear Air Act to protect people from secondhand smoke).

ucts as drugs would logically result in a ban on such products.⁸⁵ Under the FD&C Act, approval of a new drug application (NDA) requires that a drug product be proven "safe and effective" for its intended use.⁸⁶ Because of the documented health hazards of smoking, this NDA requirement would pose a serious obstacle for the future marketing of tobacco products as drugs.

Even if this premarket approval hurdle could somehow be surmounted,⁸⁷ the FDA would have to require that cigarettes be available only on a doctor's prescription, at least if it wanted to control their advertising.⁸⁸ Instead, the Agency has opted to take a different and more dubious regulatory tack. As explained in the next section, the new rules would regulate tobacco products as medical devices,⁸⁹ specifically as "restricted" medical de-

85. See 60 Fed. Reg. 41,314, 41,348 (1995) ("The products would be unapproved new drugs, and as such, FDA could require their removal from the market."); see also 21 U.S.C. §§ 331(d), 355(a) (1994) (prohibiting the sale of unapproved new drugs); *Public Health Cigarette Amendments of 1971: Hearings Before the Consumer Subcomm. of the House Comm. on Energy and Commerce*, 92d Cong. 239 (1972) (statement of Charles C. Edwards, Commissioner of Food and Drugs) ("[I]f cigarettes were to be classified as drugs, they would have to be removed from the market because it would be impossible to prove they were safe for their intended us[e]."); *id.* at 242 ("[L]abeling or banning cigarettes is a step that can be take[n] only by the Congress. Any such move by FDA would be inconsistent with the clear congressional intent."). The Agency also asserts that banning tobacco products would not be the most effective means of protecting the public health—it fears that the highly addictive nature of nicotine may mean adverse health consequences for smokers as a consequence of inadequate treatment for withdrawal and poor-quality black market cigarettes. See 61 Fed. Reg. 44,396, 44,398, 44,413 (1996).

86. See 21 U.S.C. § 355 (1994); 21 C.F.R. pt. 314 (1996). The Act defines "new drug" as any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). For a summary of some of the most important requirements, see Lars Noah, *Sham Petitioning as a Threat to the Integrity of the Regulatory Process*, 74 N.C. L. REV. 1, 6-10 (1995).

87. See *infra* notes 158-160 and accompanying text (discussing possible exemptions from new drug requirements).

88. See 21 U.S.C. § 352(n) (granting the FDA authority to regulate the advertising of prescription drugs); *id.* § 353(b) (requiring prescription status for drugs which are habit-forming or are not safe for use except under the supervision of physicians because of their toxicity or potentiality for harmful effect).

89. The statute defines a medical device as follows:

[A]n instrument, apparatus, . . . or other similar or related article . . . which is . . . (2) intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease, in man or other ani-

vices,⁹⁰ so that the FDA can exert control over their advertising as well as their distribution and use.⁹¹

The FDA asserts that cigarettes and smokeless tobacco products are combination drug-device products which it has the discretion to regulate as medical devices.⁹² The Agency explains this categorization by claiming first that tobacco products, because they consist of nicotine (a drug) and other components,⁹³ are combination products which together function as drug-delivery systems.⁹⁴ The FDA then lists other examples of so-called

mals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its principal intended purposes.

Id. § 321(h); see also Gary E. Gamerman, Note, *Intended Use and Medical Devices: Distinguishing Nonmedical "Devices" from Medical "Devices" Under 21 U.S.C. § 321(h)*, 61 GEO. WASH. L. REV. 806 (1993).

90. 61 Fed. Reg. at 44,405. Pursuant to the Act, the restricted device designation is appropriate if, because of a device's "potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360j(e)(1)(B) (1994); see also 21 C.F.R. § 807.3(i) (1996) (defining restricted devices as those for which the FDA has "restricted sale, distribution, or use only upon the written or oral authorization of a practitioner licensed by law to administer or use the device or upon such other conditions as the Commissioner may prescribe"); *infra* Part II.C.

91. Congress has, in general, assigned to the FTC the duty to oversee product advertising, including the advertising of tobacco products. See *supra* Part II.A.2. Under the FD&C Act, the FDA has advertising authority only over prescription drugs and "restricted" medical devices. See 21 U.S.C. § 352(n), (q) (1994).

92. See 61 Fed. Reg. at 44,403 (observing that "the device provisions offer FDA more flexibility"); *id.* at 44,414-16 (suggesting that it could have imposed many of the same restrictions by issuing regulations pursuant to its authority over drug products); see also 21 C.F.R. § 3.2(e)(1) (1996) (defining a combination product as a "product comprised of two or more regulated components, i.e., drug/device").

93. See 61 Fed. Reg. 44,619, 45,206-07 (1996) (jurisdictional statement). In the case of cigarettes, the FDA asserts that the

primary purpose of the parts of the cigarette . . . is to effectuate the delivery of a carefully controlled amount of nicotine to a site in the human body where it can be absorbed. . . . The delivery system, the nicotine-containing cigarette, must be lit to have its intended effect on the structure or function of the body, and, once lit and used, is discarded.

Id. (quoting NPRM). Smokeless tobacco products, the Agency explains, "function like infusion devices or transdermal patches that deliver continuous amounts of nicotine to the cheek tissue for absorption into the bloodstream. The device element of smokeless products is the tobacco, which contains the nicotine but is not intended to be consumed." *Id.*; see also *id.* at 45,213-16.

94. See *id.* at 45,208-18; 60 Fed. Reg. 41,314, 41,347 (1995) ("FDA considers

“pre-filled delivery systems,” such as transdermal patches, pre-filled syringes, and metered-dose inhalers (MDIs), which it asserts are comparable to tobacco products in function.⁹⁵ Finally, although it acknowledges that its Center for Drug Evaluation and Research (CDER) has primary jurisdiction over such combination products because they represent dedicated rather than generic delivery systems, the Agency asserts that it nonetheless may exercise its discretion to regulate tobacco products as medical devices.⁹⁶ Ignoring their primary mode of action as a drug, the FDA argues that CDER’s undoubted jurisdiction over pre-filled drug-delivery systems does not necessarily dictate which provisions of the FD&C Act should apply to tobacco products.⁹⁷

Although the Agency certainly may select from among the available statutory provisions those most suited to its particular regulatory goal, this discretionary power is limited by the terms of the statutory provisions themselves. For a number of reasons, the FDA cannot logically treat tobacco products as medical devices, let alone “restricted” devices. For instance, in order to sustain its drug-delivery system argument, the Agency must acknowledge and distinguish relevant regulatory precedents. The FDA has required that smoking deterrent products such as transdermal nicotine patches and nicotine chewing gum, which are virtually indistinguishable from cigarettes in their function

articles . . . whose primary purpose is the delivery of a drug, and that are distributed with a drug product to be drug delivery systems.”); *see also* Anita Manning, *AMA Calls for Tobacco Regulation*, USA TODAY, June 8, 1994, at 1A (The AMA labeled nicotine “the most addictive drug we know Cigarettes are no different than syringes. They are a drug delivery device. . . . They should be regulated as we regulate morphine and heroin.”). In reaching its conclusion, the FDA purports to rely on the Intercenter Agreement Between the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH), § VII(A)(1)(b) (Oct. 31, 1991) (hereinafter the “Intercenter Agreement”); *see* 61 Fed. Reg. at 45,211.

95. *See* 61 Fed. Reg. at 45,206, 45,211; 60 Fed. Reg. at 41,521. In the preamble accompanying the final regulations, the FDA also lists catheter flush solution and intravenous infusion pumps pre-filled with a simple diluent as combination products it has regulated as devices.

96. *See* 61 Fed. Reg. 44,396, 44,403 (1996).

97. *See id.* at 44,400-03 (claiming that the FDA has the authority to regulate tobacco products under either the drug or medical device provisions of the Act, or both, as it deems appropriate); *see also* 21 C.F.R. § 3.1 (1996) (stating that “[n]othing in this section prevents FDA from using any agency resources it deems necessary to ensure adequate review of the safety and effectiveness of any product, or the substantial equivalence of any device to a predicate device”).

and intended effect, satisfy NDA requirements prior to marketing.⁹⁸ With regard to these products, the Agency chose not to categorize either product as a medical device. Indeed, the FDA has classified all smoking deterrent products as drugs.⁹⁹

In addition, the FD&C Act was amended in 1990 to require that a product be regulated according to its "primary mode of action."¹⁰⁰ For example, ordinary empty syringes are regulated as medical devices, while pre-filled syringes are regulated as drugs. Under this rationale, dedicated drug-delivery devices clearly ought to be regarded as drug products, not medical devices. As the FDA itself notes, the 1991 Intercenter Agreement between CDER and the Center for Devices and Radiological Health (CDRH) supports this conclusion,¹⁰¹ but it nonetheless believes that cigarettes and smokeless tobacco products should be regulated as medical devices.¹⁰² In the past, the FDA successfully has used counterintuitive classifications of products in order to maximize its regulatory control, but these efforts almost always

98. The NDA for Nicorette, a prescription drug chewing gum product containing 2 mg. of nicotine per piece, was approved in 1984; the product is indicated "as a temporary aid to the cigarette smoker seeking to give up his or her smoking habit while participating in a behavior modification program under medical or dental supervision." 49 PHYSICIANS' DESK REFERENCE 2346 (1995); see also *Nicotine Nasal Spray Aims to Halt Smoking*, N.Y. TIMES, Mar. 26, 1996, at C7 ("The nicotine nasal spray . . . reaches the bloodstream faster than the nicotine in the gum or patch, offering the potential of almost immediate relief of cigarette cravings.").

99. See 58 Fed. Reg. 31,236 (1993). The final rule establishes that any smoking deterrent product for over-the-counter (OTC) use is not generally recognized as safe and effective and is misbranded. See 21 C.F.R. § 310.544. Any such nonprescription products containing active ingredients are new drugs and require a new drug application or an abbreviated new drug application. See *id.* The FDA recently approved OTC sale of Nicorette gum and the Nicotrol patch. See Amal K. Naj, *J&J Nicotine Patch Is Cleared for Sale Over the Counter*, WALL ST. J., July 5, 1996, at B10; John Schwartz, *FDA Approves Nicorette Sales*, WASH. POST, Feb. 10, 1996, at A7.

100. Safe Medical Devices Act of 1990, Pub. L. No. 101-629, § 16(a), 104 Stat. 4511, 4526 (codified as amended at 21 U.S.C. § 353 (1994)) (requiring the development of intercenter agreements to regulate products that constitute a combination of a drug, device, or biologic); 21 C.F.R. § 3.4 (summarizing Intercenter Agreements).

101. See M-D-D-I REPORTS ("The Gray Sheet"), Nov. 25, 1991, at 6-11 (Under the Intercenter Agreement, a "device containing a drug substance as a component with the primary purpose of the combination product being to fulfill a drug purpose is a combination product and will be regulated as a drug by CDER.").

102. See 61 Fed. Reg. at 44,402-03. Despite its decision to regulate cigarettes as medical devices, the FDA appears to assign all tobacco products to its drug center; for instance, it requires that certain labeling and advertising be forwarded to CDER. See 21 C.F.R. § 897.30(a)(2).

involved treating medical devices and other products as drugs.¹⁰³ Here, for perhaps the first time, the FDA is playing this semantic game in reverse, trying to force an apparent drug product into the less exacting medical device category.¹⁰⁴

By reversing its position on the proper classification of dedicated drug-delivery systems, at least in the treatment of tobacco products as medical devices, the FDA sets a dubious precedent for other products. At present, for instance, the Agency regards MDI actuators and infusion pumps as drug-delivery systems within CDER's jurisdiction.¹⁰⁵ If the tobacco regulations reflect a revised FDA interpretation of the statute, MDI actuators and other such articles could be recharacterized as medical devices subject to less stringent controls. (Of course, the FDA could re-

103. The FDA has used the broad statutory definition of "drug" on numerous occasions to regulate products that otherwise would have been subject to the less stringent food, device, or cosmetic provisions of the Act. *See, e.g.*, *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 799 (1969) (holding that, in view of the statutory purpose, "it was entirely reasonable for the Secretary to determine that the discs, like the antibiotics they serve, are drugs and similarly subject to pre-clearance certification"); *AMP Inc. v. Gardner*, 389 F.2d 825, 826 (2d Cir. 1968) (upholding the FDA's categorization of a nylon vessel clamp (ligature) as a drug rather than a device); *cf. National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 329 (2d Cir. 1977) (rejecting an FDA attempt to regulate high potency vitamins as drugs); *United States v. Article . . . OVA II*, 414 F. Supp. 660, 661-65 (D.N.J. 1975) (rejecting an FDA attempt to categorize a home pregnancy kit as a drug), *aff'd*, 535 F.2d 1248 (3d Cir. 1976). The FDA also has declared that all intrauterine devices (IUDs) which incorporate heavy metals or other chemicals for contraceptive purposes were "new drugs" within the meaning of the FD&C Act. *See* 21 C.F.R. § 310.502(a); 38 Fed. Reg. 6137 (1973).

104. The Agency has, on occasion, asserted device status for products that arguably are completely beyond its jurisdiction. *See, e.g.*, *United States v. Undetermined Number of Unlabeled Cases*, 21 F.3d 1026, 1028-29 (10th Cir. 1994) (in vitro diagnostic specimen collection containers used for insurance underwriting purposes); *United States v. 25 Cases . . . "Sensor Pad"*, 942 F.2d 1179, 1182 (7th Cir. 1991) (self-examination devices to help detect breast cancer); *United States v. 23, More or Less, Articles*, 192 F.2d 308, 310 (2d Cir. 1951) (self-help phonograph records); *United States v. 22 Rectangular . . . MD-200*, 714 F. Supp. 1159, 1164 (D. Utah 1989) (sterilizer machine for surgical instruments).

105. At present, FDA-regulated firms must clear drug-delivery systems through CDER. *See, e.g.*, M-D-D-I REPORTS ("The Gray Sheet"), Nov. 28, 1994, at 6-7 (describing a California company which was developing a new aerosol cartridge delivery system for use with a variety of drugs and planned to file an investigational new drug application before beginning clinical trials); M-D-D-I REPORTS ("The Gray Sheet"), Apr. 4, 1994, at I&W-10 (quoting CDRH official as advising device manufacturers that "[m]any drug delivery systems have been on hold" because of questions about cross-labeling of the devices and the drugs that they deliver).

spond that tobacco products are *sui generis*, a case to be treated separately from other drug-delivery systems and that, in the future, it will deal with other such products on a case-by-case basis.) There are important differences in the rigor of the approval and in the oversight processes between the “drug” and “device” categories.¹⁰⁶ Certain combination products are, for safety reasons, better treated as drugs than as devices. Arguably, products such as transdermal patches and syringes pre-filled with biologics genuinely require the more stringent controls that accompany a “drug” designation.

C. Tobacco Products as “Restricted” Medical Devices

The FDA next asserts that cigarettes and smokeless tobacco products are not only medical devices, but are also properly characterized and regulated as “restricted” medical devices. The FD&C Act authorizes the Secretary to promulgate regulations restricting a device’s “sale, distribution, or use . . . if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.”¹⁰⁷ The Agency asserts that all of its restrictions on distribution and advertising are necessary to reduce tobacco products’ potentiality for harmful effect.¹⁰⁸

The regulations contain a number of provisions aimed at substantially reducing the sale and distribution of tobacco products to minors. The FDA will require, among other things, that

106. See, e.g., Peter Barton Hutt et al., *The Standard of Evidence Required for Premarket Approval Under the Medical Device Amendments of 1976*, 47 FOOD & DRUG L.J. 605 (1992); Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 HARV. J.L. & TECH. 1 (1989); Lawrence S. Makow, Note, *Medical Device Review at the Food and Drug Administration: Lessons from Magnetic Resonance Spectroscopy and Biliary Lithotripsy*, 46 STAN. L. REV. 709 (1994).

107. 21 U.S.C. § 360j(e)(1)(B) (1994).

108. See 61 Fed. Reg. 44,396, 44,405 (1996) (“The agency has determined that unless measures are taken now to prohibit the sale and promotion of [tobacco] products to young people under the age of 18, there cannot otherwise be reasonable assurance of safety.”). The FDA argues, for example, that the photographic identification requirements are necessary to prevent sales to those under the age of 18. See *id.* at 44,439-40; see also *id.* at 44,444 (explaining the necessity for a prohibition on the use of nontobacco product names).

retailers verify the age of purchasers by demanding picture identification,¹⁰⁹ prohibit vending-machine sales in certain locations,¹¹⁰ and prohibit the distribution of free samples of both cigarettes and smokeless tobacco products.¹¹¹ The FDA may have difficulty justifying its point-of-sale restrictions under its authority to limit the distribution of restricted devices. The reach of the statute may not be as great as the Agency would like, but regulations governing vending-machine sales, photo identification restrictions, and the like may be better left to state control.¹¹²

For most medical devices, the FTC has advertising authority pursuant to the FTC Act, which prohibits false or deceptive advertising.¹¹³ In 1976, Congress gave the FDA limited authority to regulate the advertising of restricted medical devices.¹¹⁴

109. See 21 C.F.R. § 897.14(b)(1).

110. See *id.* § 897.14(c).

111. See *id.* § 897.16(a)(2)(i). The FDA originally had proposed banning mail-order sales, but it decided to drop this restriction as unnecessary. See 61 Fed. Reg. at 44,458-59. A number of small tobacco retailers maintain sales sites on the "World Wide Web" through which they market lesser-known cigarette brands in the United States and abroad. Many of these retailers make no attempt to verify the age of their customers or to include the required Surgeon General's Warning on their Internet sites. See Timothy Noah, *Cigarettes Are Being Marketed Through Web Sites on the Internet*, WALL ST. J., Jan. 24, 1996, at B2; see also 61 Fed. Reg. at 44,501-02 (discussing promotional questions posed by the use of the Internet).

112. All 50 states currently ban the sale of tobacco products to children under the age of 18, but enforcement of the state statutes has been notoriously lax. See Barnaby J. Feder, *A Study Finds that Teen-Agers Are Buying Cigarettes with Ease*, N.Y. TIMES, Feb. 16, 1996, at A10 (According to a recent government survey, the percentage of teenage smokers between the ages of 12 and 17 who have successfully purchased their own cigarettes rose from 58% in 1989 to 62% in 1993.). HHS recently promulgated a final rule requiring all states to maintain and enforce laws prohibiting the sale of tobacco products to persons under the age of 18 as a condition for continuing to receive federal block grants. See 61 Fed. Reg. 1492 (1996) (to be codified at 45 C.F.R. §§ 96.122-130) (requiring random, unannounced state inspections of tobacco product vendors and demanding that states maintain minimum compliance levels in order to continue to receive grants).

113. See 15 U.S.C. § 52 (1994); see also *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1498 (1st Cir. 1989) (upholding an FTC order requiring that an advertising claim for a device promising permanent removal of unwanted hair be supported by at least one well-controlled scientific study).

114. See Medical Device Amendments of 1976, Pub. L. No. 94-295, § 3(e)(1), 90 Stat. 539, 577-78 (codified at 21 U.S.C. § 352(q), (r) (1994)). This power and others apply only to those restricted devices identified as such by the FDA through the issuance of regulations under § 520(e) of the FD&C Act. See 21 U.S.C. § 360j(e) (1994). Other special provisions applicable to restricted devices require the submit-

Fourteen years earlier, the Agency had acquired advertising jurisdiction over prescription drug products.¹¹⁵ It is not clear why Congress chose to specify “restricted” rather than “prescription” devices, though the available legislative history suggests that these terms were viewed as synonymous.¹¹⁶

The FDA’s implementation of this authority over the last two decades has only contributed to the confusion about its meaning. Initially, the Agency announced that all existing prescription devices would be regarded as restricted medical devices.¹¹⁷ Although invalidated on procedural grounds,¹¹⁸ this contemporaneous interpretation of the statute—equating “restricted” with prescription—deserves some judicial deference.¹¹⁹

The FDA never promulgated general regulations to imple-

sion of all labeling and samples of advertising, *see id.* § 360(j)(1)(B)(i), and authorize broader FDA factory inspections, *see id.* § 374(a); *see also id.* §§ 360d(a)(2)(B)(v), 360e(d)(1)(B)(ii) (providing that performance standards and premarket approval requirements must take account of any special device restrictions).

115. *See* Drug Amendments of 1962, Pub. L. No. 87-781, § 131(a), 76 Stat. 780, 791-92 (codified at 21 U.S.C. § 352(n) (1994)); *see also* Lars Noah, *Death of a Salesman: To What Extent Can the FDA Regulate the Promotional Statements of Pharmaceutical Sales Representatives?*, 47 *FOOD & DRUG L.J.* 309, 322-26 (1992). The FTC is responsible for regulating the advertising of nonprescription drug products. *See* 36 Fed. Reg. 18,539 (1971) (announcing a memorandum of understanding between the FDA and the FTC).

116. *See* H.R. REP. NO. 94-853, at 25 (1976) (“In addition to authorizing the Secretary to limit a device to prescription status, conditions on sale or distribution could include use only within hospitals or clinics. . . . Also, . . . certain devices which would not be appropriate for use by the ordinary layman could be authorized for use by trained nurses and technicians.” (emphasis added)); S. 510, 94th Cong. §§ 707, 708(a) (1975) (this earlier version of the legislation referred only to “prescription devices”), reprinted in 121 CONG. REC. 10701 (1975). The FDA asserts that the restricted device provision, though a “counterpart” to the prescription drug advertising provision, “is significantly broader.” *See* 61 Fed. Reg. at 44,405.

117. *See* 41 Fed. Reg. 22,620, 22,621 (1976) (“Restricted devices include all prescription devices as now defined in 21 C.F.R. § 801.109 . . .”). This cross-reference remains in the regulations. *See* 21 C.F.R. § 807.3(i) (1996).

118. *See In re* Establishment Inspection Portex, Inc., 595 F.2d 84, 86 (1st Cir. 1979); *Becton, Dickinson & Co. v. FDA*, 589 F.2d 1175, 1181 (2d Cir. 1978). Both cases involved the FDA’s broader factory inspection authority over restricted devices. *See* 21 U.S.C. § 374(a).

119. *See, e.g.,* *General Elec. Co. v. Gilbert*, 429 U.S. 125, 142 (1976); *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 274-75 (1974); *Les v. Reilly*, 968 F.2d 985, 989 (9th Cir. 1992); *Rhodia, Inc. v. FDA*, 608 F.2d 1376, 1379 (D.C. Cir. 1979); *United States v. Undetermined Quantities . . . Exachol*, 716 F. Supp. 787, 795 (S.D.N.Y. 1989); *cf. Rust v. Sullivan*, 500 U.S. 173, 187 (1991) (deferring to revised interpretation of statute where supported by “reasoned analysis”).

ment its authority over restricted medical devices. In 1980, it issued a proposed regulation,¹²⁰ but this was withdrawn the following year.¹²¹ In recent years the Agency has repeatedly announced its plans to issue a rulemaking proposal on this issue,¹²² but the FDA withdrew this promise just one week after the issuance of the proposed tobacco regulations.¹²³

The FDA has successfully asserted its restricted device authority on only one occasion; when it promulgated special rules for the labeling and distribution of hearing aids in 1977.¹²⁴ The legal basis for this decision is hardly obvious.¹²⁵ The preamble to the final regulation cited the restricted device

120. See 45 Fed. Reg. 65,619, 65,624 (1980) (to be codified at 21 C.F.R. § 899.60) (proposed Oct. 3, 1980) (defining the advertising limitation on restricted devices in its entirety as follows: "Any advertisement for a restricted device may not recommend or imply any use that is not in the labeling for the restricted device.").

121. See 46 Fed. Reg. 57,569 (1981). In explaining its withdrawal of the proposal, the Agency cited comments that the proposed regulations were overly burdensome and that the FDA had exceeded its authority under § 520(e) of the FD&C Act. See *id.*

122. See, e.g., 60 Fed. Reg. 23,304, 23,310 (1995) (Semi-annual Unified Regulatory Agenda) ("FDA would propose to include in this [restricted] category devices such as those that pierce or penetrate the skin, implantable devices, devices that introduce medicinal gas or energy into the body and devices that are used for diagnosis that must be interpreted or analyzed by a qualified health professional."). Publication of such a notice of proposed rulemaking was anticipated sometime during September of 1995. See *id.* Earlier timetables suggested a proposal by May of 1994. See 59 Fed. Reg. 20,355, 20,356 (1994).

123. See 60 Fed. Reg. 60,033 (1995) (noting that the plan was withdrawn on Aug. 16, 1995).

124. See 42 Fed. Reg. 9286, 9293-94 (1977) (codified as amended at 21 C.F.R. §§ 801.420-421 (1996)). The regulations do not explicitly characterize hearing aids as restricted devices. See *id.*; see also 21 C.F.R. § 874.3300 (1996) (classification regulation). Nonetheless, the FDA now refers to its regulation of this device as precedent for its use of the restricted device provisions of the statute. See 61 Fed. Reg. 44,396, 44,406, 44,408 (1996).

125. The regulations were challenged unsuccessfully. See 42 Fed. Reg. 40,215 (1977) (agreeing to a stay of the effective date pending the outcome of this litigation); *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795, 801 n.2 (N.J. 1978) (noting that the district court had upheld the regulations). Manufacturers have attempted to rely on the FDA's assertion of jurisdiction as a basis for challenging the FTC's continued supervision of their advertising. See *In re Dahlberg*, 1995 U.S. Dist. LEXIS 19697, at *13-*15 (D. Minn. Mar. 31, 1995) (rejecting this argument). Similarly, companies have argued that the FDA's regulations preempt continued state supervision. See *Kievlan v. Dahlberg Elecs.*, 144 Cal. Rptr. 585, 590 (App. 1978) (concluding that the FDA had not in fact classified hearing aids as restricted devices); see also *Massachusetts v. Hayes*, 691 F.2d 57, 60-64 (1st Cir. 1982); *Smith v. Pingree*, 651 F.2d 1021, 1023-25 (5th Cir. 1981).

provision as statutory authority for the regulations, but the proposal never did so because its publication pre-dated passage of the MDA by one month.¹²⁶ Moreover, the final rules pre-dated the successful judicial challenges to the Agency's policy of treating all prescription devices as restricted medical devices.¹²⁷ Finally, to the extent that this regulation serves as any meaningful guidance for the restricted device provision, it again reflects an assumption that the term "restricted" refers only to those medical devices whose distribution has been limited to prescription or professional sale. The FDA has not, however, restricted access to tobacco products in any such fashion.

Thus, after twenty years of disuse, the FDA suddenly and creatively seizes upon its restricted device authority as a convenient basis for controlling the advertising of tobacco products; products which heretofore have never been regarded as medical devices, much less restricted devices. Putting hearing aids to one side, the Agency has not assumed control over the advertising of any of the other thousands of classes of medical devices currently on the market.¹²⁸ This is not a case of creatively squeezing a nondevice product into an existing medical device pigeonhole. Instead, the FDA is effectively rediscovering a narrow statutory category solely to control a nondevice product. Ironically, once

126. See 41 Fed. Reg. 16,756, 16,758 (1976) (though anticipating the use of its restricted device authority under the then-pending legislation); see also 21 U.S.C. § 360j(e) (1994) (specifying requirements for NPRMs under the restricted device provision); *In re Establishment Inspection Portex, Inc.*, 595 F.2d 84, 86 (1st Cir. 1979) ("Comment on the prescription device regulation obviously would not have been addressed to the additional strictures imposed on the industry by the 1976 amendment."); *Becton, Dickinson & Co. v. FDA*, 589 F.2d 1175, 1181 (2d Cir. 1978) ("Congress was careful to provide a rulemaking procedure in which all participants would have a full opportunity to present their views and analyses of the data underlying the proposed regulation."); cf. *Chocolate Mfrs. Ass'n v. Block*, 755 F.2d 1098, 1104-07 (4th Cir. 1985) (holding that, unless the final regulations are a "logical outgrowth" of the original proposal, the Administrative Procedure Act requires publication of a revised NPRM to allow for additional comments).

127. See *supra* note 118. In the context of more recent proposals, the FDA did not once characterize hearing aids as "restricted" devices. See 58 Fed. Reg. 59,695, 59,696 (1993) (announcing plans to propose revisions to the current distribution and labeling regulations).

128. See Sandra J.P. Dennis, *Promotion of Devices: An Extension of FDA Drug Regulation or a New Frontier?*, 48 FOOD & DRUG L.J. 87, 93-94 (1993); Ronald M. Johnson, *FDA Regulatory Actions and Future Plans for Medical Device Promotion and Advertising*, 47 FOOD & DRUG L.J. 291, 292 (1992).

the FDA asserts its restricted device authority to regulate advertising, the FTC—the one agency that Congress understood as having the authority to regulate the advertising of tobacco products—automatically loses its general jurisdiction over those products.¹²⁹

*D. FDA Authority to Regulate Advertising
of Restricted Devices*

The new regulations prohibit the placement of outdoor advertising for tobacco products, including billboards and posters, within 1,000 feet of any playground or school,¹³⁰ and they limit all tobacco product advertising in publications with an under eighteen-year-old target audience to black print on a white background only, sometimes characterized as a “text only” or “tombstone” format.¹³¹ The regulations also prohibit the marketing, distribution, sale, or gift of any items, other than the tobacco products themselves, bearing the product name, logo, selling message or other “indicia of product identification,” and they prevent tobacco product manufacturers, distributors, and retailers from sponsoring any sporting, musical or other social events using brand-names or other identifying information.¹³²

The FDA’s power to regulate the advertising of restricted devices is not unlimited. The scant legislative history of the restricted device provision suggests that Congress meant to give the FDA advertising authority over restricted devices that was co-extensive with its authority over prescription drugs.¹³³ But

129. See 21 U.S.C. § 352(r) (“[N]o advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of [the FTC Act,] sections 52 through 55 of title 15.”). The FTC would, however, retain its more specific authority over, for instance, smokeless tobacco products because it derives from a statute other than the FTCA. See *supra* note 54.

130. See 21 C.F.R. § 897.30(b).

131. See *id.* § 897.32(a). This restriction applies when minors account for either 15% of a publication’s readership or two million readers of a publication.

132. See *id.* § 897.34. The regulations would, however, permit such events to be sponsored in the name of the corporation which manufactures the products, provided that the corporate name had been registered before January 1, 1995. See *id.* § 897.34(c).

133. See S. REP. NO. 94-33, at 17 (1975); see also 45 Fed. Reg. 65,619, 65,624 (1980) (to be codified at 21 C.F.R. § 899.60) (proposed Oct. 3, 1980) (defining the

the Agency has imposed far more intrusive restrictions on tobacco product advertising than are permissible in the realm of prescription drugs. For example, the use of prescription brand-names on reminder advertisements to doctors currently is permissible;¹³⁴ yet the FDA will eradicate the use of tobacco product brand-names on any item other than the products themselves.¹³⁵

The restrictions on the format and content of print advertisements raise similar questions. The Agency again relies on the broad language of the statute's restricted device provisions to support these limitations, noting that the FDA enjoys the power to control the advertising of such products.¹³⁶ But the FDA has never attempted to impose restrictions of this sort on prescription drugs or restricted devices, and the Agency probably would not succeed if it tried.¹³⁷

The proposals would have required that tobacco product manufacturers annually spend \$150 million on a national educational campaign to discourage minors from using cigarettes and smokeless tobacco.¹³⁸ The final regulations do not include such a requirement, but the Agency clearly expressed its intention of separately requiring that companies engage in an educational campaign.¹³⁹

advertising limitation on restricted devices in its entirety as follows: "Any advertisement for a restricted device may not recommend or imply any use that is not in the labeling for the restricted device.", *withdrawn*, 46 Fed. Reg. 57,569 (1981). In fact, the FDA's authority over restricted device advertising actually may be somewhat less extensive than its existing authority over prescription drugs. See Dennis, *supra* note 128, at 94. *But cf.* 61 Fed. Reg. 44,396, 44,407-08 (1996) (claiming greater authority over restricted devices); *id.* at 44,415 (arguing that its authority to regulate drug advertising is extensive).

134. See 21 C.F.R. § 202.1(e)(2)(i) (1996).

135. See 21 C.F.R. § 897.34.

136. See 61 Fed. Reg. at 44,406-07 ("The effectiveness of the restrictions on youth access would be substantially diminished if the manufacturers were free to entice children and adolescents to circumvent the access restrictions.").

137. Courts have remanded overbroad FDA injunctions against promotional activities by drug manufacturers. See, e.g., *United States v. Vitasafe Corp.*, 345 F.2d 864, 870-71 (3d Cir. 1965).

138. See 60 Fed. Reg. 41,314, 41,326-28 (1995) (to be codified at 21 C.F.R. § 897.29) (proposed Aug. 11, 1995). Funding among the different manufacturers would have been in shares proportionate to their total respective advertising and promotional budgets, and the bulk of this extensive campaign would have to appear on television.

139. See 61 Fed. Reg. at 44,538, 44,590; see also Timothy Noah, *Clinton's Tobacco*

Even if the restricted medical device categorization properly applies to tobacco products, it is not at all clear that an industry-funded educational campaign would be permissible under the authority delegated by Congress. In its NPRM, the Agency cited several provisions of the Act in support of this requirement,¹⁴⁰ and it asserted that the various statutory provisions, taken in combination, would support this remedy.¹⁴¹ The FDA also noted that courts have ratified its interpretation of the FD&C Act as giving it the authority to require dissemination of information regarding drug products.¹⁴² But the statute expressly forbids

Rule Restricts Ads in Media Deemed Accessible to Minors, WALL ST. J., Aug. 26, 1996, at B2 ("FDA Commissioner David Kessler said he still anticipates the campaign will consist largely of TV ads, and that it will cost between \$100 million to \$150 million.").

140. Section 520(e) sets out the FDA's restricted device authority. See 21 U.S.C. § 360j(e) (1994); see also *supra* Part II.C. Sections 502(a) and (q) of the Act provide that a device and a restricted device, respectively, are misbranded if their labeling is false or misleading in any particular. See 21 U.S.C. § 352(a), (q). Neither section, however, specifically authorizes the FDA to require corrective advertising or educational programs to correct misbranding. Section 201(n) of the Act instructs the Agency, in determining whether labeling or advertising is false or misleading, to consider "the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article." *Id.* § 321(n). The Act also contains a notification provision authorizing the Secretary, upon a determination that a device presents "an unreasonable risk of substantial harm to public health," to require notification to health professionals, device users, and others, of the risk involved, see *id.* § 360h(a)(1)-(2), but the Agency did not cite this section in support of its proposals, though it apparently discovered the potential utility of this provision during the course of the rulemaking process. See 61 Fed. Reg. at 44,538.

141. According to the FDA, the proposed campaign

is consistent with these statutory provisions because it is intended to help ensure that cigarette and smokeless tobacco product advertising and labeling is not false or misleading and to counteract the appeal of these products previously created by advertising, thereby providing important, material information regarding the consequences of cigarette or smokeless tobacco product use by young people.

60 Fed. Reg. 41,314, 41,351 (1995).

142. See *id.* (citing *Pharm. Mfrs. Ass'n v. FDA*, 484 F. Supp. 1179, 1183-86 (D. Del.) (finding statutory authorization in FD&C Act §§ 201(n), 502(a), (f), & 701(a)), *aff'd*, 634 F.2d 106 (3d Cir. 1980) (per curiam)). In *Pharmaceutical Manufacturers*, the drug industry unsuccessfully challenged a proposed regulation requiring that a patient package insert (PPI) accompany conjugated estrogen products. The decision concerned labeling, not advertising. The opinion focused on the FDA's authority over drug product labeling and the requirement that labels not be misleading. See *Pharm. Mfrs. Ass'n*, 484 F. Supp. at 1185-86. Although the FDA undoubtedly has authority over drug and medical device labeling, this authority does not translate into the

prior Agency approval of restricted device advertising.¹⁴³

Perhaps in recognition of these weaknesses, the Agency dropped the educational campaign requirement from the final regulations. Nonetheless, the FDA announced that, because tobacco products now are subject to medical device requirements, it would employ its statutory authority to demand "notification" of hazards.¹⁴⁴ The notification provision does not, however, support the FDA's effort to establish an industry-sponsored public education campaign. Congress authorized the FDA to require notification of users when substantial hazards with a marketed device subsequently come to light.¹⁴⁵ In effect, notification would represent part of a recall strategy, for instance to advise physicians and patients of potential hazards and the possible need to replace an implanted device.¹⁴⁶ The FDA's proposed educational campaign would not simply advise existing device users of some newly discovered hazard but instead would attempt to discourage would-be users.¹⁴⁷

A few states currently sponsor public education programs. In 1988, voters in California approved a tax increase on tobacco products to finance a state-sponsored anti-smoking media campaign.¹⁴⁸ With the \$150 million raised to date, the program has significantly reduced the number of smokers in the state.¹⁴⁹

power to demand corrective or educational advertising, particularly when such remedies are not specifically authorized by the statute.

143. See 21 U.S.C. § 352(r) ("Except in extraordinary circumstances, no regulation issued under this paragraph [governing restricted devices] shall require prior approval by the Secretary of the content of any advertisement . . .").

144. See 61 Fed. Reg. at 44,538.

145. See 21 U.S.C. § 360h(a) (authorizing the issuance of an order to notify health professionals and users if a device "presents an unreasonable risk of substantial harm to public health" and if "no more practicable means is available . . . to eliminate such risk"); 49 Fed. Reg. 11,716 (1984) (announcing the availability of a draft guideline on Medical Device Notification and Voluntary Safety Alert).

146. As the FDA itself notes, "section 518 of the act [21 U.S.C. § 360h] applies to the recall of a device, not its advertising." 61 Fed. Reg. at 44,437; cf. 21 U.S.C. § 360h(e)(1) (authorizing the issuance of a recall order including notification of health professionals).

147. Elsewhere, in justifying an exemption from a statutory labeling requirement, the FDA explained that "the public health would not be advanced by requiring adequate directions for use." See 61 Fed. Reg. at 44,465.

148. See CAL. REV. & TAX. CODE §§ 30121-30130 (West 1994); Kennedy Wholesale, Inc. v. State Bd. of Equalization, 806 P.2d 1360, 1362-67 (Cal. 1991) (rejecting challenges to Proposition 99).

149. See Michael Massing, *How to Win the Tobacco War*, N.Y. REV. BOOKS, July

Because the FDA clearly lacks the power to tax cigarettes to fund its own public education campaign,¹⁵⁰ the Agency must couch its unprecedented national program as a corrective advertising requirement imposed through its authority to demand that device manufacturers notify users of substantial hazards.

* * * * *

More than thirty years ago, the FTC's cigarette warning regulation prompted a more moderate legislative response.¹⁵¹ The FDA may hope to trigger a similar response this time, as it did unwittingly two decades ago when it attempted to restrict sales of products sweetened with saccharin. In 1977, the FDA proposed prohibiting nearly all uses of saccharin because of a reported association with bladder cancer in animal studies.¹⁵² Congress intervened in the rulemaking process by placing a moratorium on the Agency's proposed rule and requiring instead that food products containing saccharin include a warning la-

11, 1996, at 32, 36 ("This drive has had remarkable results. Californians have quit smoking at more than twice the national rate The rate of smoking among twelve- to seventeen-year-olds has not fallen as quickly, but, at nearly 11 percent, it is still roughly half that for the nation as a whole."); see also Bob Hohler, *U.S. Examines State's Youth Tobacco Effort, White House May Model Program After Massachusetts Campaign*, BOSTON GLOBE, Aug. 8, 1995, at 3 (describing a similar program in Massachusetts); Suein L. Hwang, *Slick New Ads By Drug Firms Decry Smoking*, WALL ST. J., May 21, 1996, at B1, B9 (describing the success of the California campaign and suggesting that a new wave of advertisements by companies marketing smoking cessation drug products also may succeed in encouraging efforts to quit).

150. See U.S. CONST. art. I, § 8 (reserving for Congress the "Power To lay and collect Taxes, Duties, Imposts and Excises"); 26 U.S.C. § 5701 (1994) (imposing federal taxes on cigarettes and other tobacco products). The FDA also could not exact a "user fee" without special statutory authorization. See *National Cable Television Ass'n v. United States*, 415 U.S. 336, 340-41 (1974).

151. See *supra* notes 61-74 and accompanying text. More generally, after activist FTC behavior in the 1970s, see, e.g., *National Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672, 698 (D.C. Cir. 1973), Congress amended the governing statute to clarify and constrain the Commission's rulemaking authority. See *Magnuson-Moss Warranty-Federal Trade Commission Improvement Act*, Pub. L. No. 93-637, § 109(a), 88 Stat. 2189 (1975) (codified at 15 U.S.C. § 2309 (1994)); see also JERRY L. MASHAW ET AL., *ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM* 428-29 (3d ed. 1992) (describing subsequent congressional efforts to restrain the FTC).

152. See 42 Fed. Reg. 19,996, 20,002 (1977). The Agency's proposal would have allowed saccharin to be marketed only as an OTC drug product and with an appropriate cancer warning on the label. See *id.* at 20,004.

bel.¹⁵³ Perhaps a similar fate will befall the FDA's tobacco initiative, though this time Congress was content to await finalization of the proposals.

The FDA's initiative appears vulnerable to judicial reversal on a variety of statutory grounds, though ultimately this may be entirely beside the point. The Agency may hope simply to prompt congressional action. From that perspective, judging by the industry's suggestions for a less burdensome legislative compromise, the initiative already represents a partial success.¹⁵⁴ On the other hand, the FDA should not be free to ignore the outer boundaries of its delegated authority in pursuit of a well-meaning crusade against a public health problem. Imagine that the Agency next decided to tackle handgun control or violence in children's television programming, secure in the knowledge that such an initiative might convince Congress to legislate a compromise but would never survive long enough to undergo careful judicial scrutiny. Although these illustrations seem fanciful, FDA action might not be entirely frivolous or implausible under its broad statutory authority to regulate medical devices.¹⁵⁵

153. See Saccharin Study and Labeling Act, Pub. L. No. 95-203, § 4, 91 Stat. 1451, 1452 (1977) (codified at 21 U.S.C. § 343(o)(1) (1994)). The Act prohibits the Agency from (1) revoking or amending any interim food regulations applicable to saccharin, or (2) taking any other action to prohibit or restrict the sale or distribution of saccharin or any food, drugs, or cosmetics which lawfully contain saccharin solely on the basis of any carcinogenic or toxic effects revealed by studies available before the date of enactment. See *id.* § 3, 91 Stat. at 1452; see also Pub. L. No. 102-142, tit. 6, 105 Stat. 878, 910 (1991) (extending moratorium until May 1, 1997); Richard A. Merrill & Michael R. Taylor, *Saccharin: A Case Study of Government Regulation of Environmental Carcinogens*, 5 VA. J. NAT. RESOURCES LAW 1 (1985).

154. See Alix M. Freedman & Suein L. Hwang, *Legislation Plan on Tobacco Advances*; WALL ST. J., Aug. 26, 1996, at A2 (describing proposal which would strip the FDA of jurisdiction, enact many of the Agency's restrictions on access and advertising, and insulate manufacturers from tort liability in exchange for significant contributions into an administrative compensation system); Suein L. Hwang & Timothy Noah, *Tobacco: Philip Morris Proposes Curbs on Sales to Kids*, WALL ST. J., May 16, 1996, at B1 (describing an industry sponsored proposal for certain advertising restrictions in exchange for a provision explicitly stripping the FDA of jurisdiction); see also Timothy Noah & Laurie McGinley, *The FDA's David Kessler Savors Small Victory Against Tobacco*, WALL ST. J., Mar. 14, 1996, at B1 (reporting that one company agreed to abide by most of the FDA's proposed restrictions as part of a settlement of tort claims brought against it).

155. See 21 U.S.C. § 321(h) (1994); *supra* note 104 (citing cases where the FDA asserted jurisdiction over products not generally thought of as medical devices); Gamerman, *supra* note 89, at 810-15; cf. Jeff Nesmith, *House Refuses to Restore Gun*

III. CONSEQUENCES OF A DEVICE DESIGNATION

The classification of tobacco products as medical devices—restricted or otherwise—will have significant implications wholly apart from the specific restrictions sought by the Agency at this point. Indeed, the FDA's announced plans to pursue the industry-sponsored educational campaign through its notification authority demonstrate the potential breadth of the Agency's power over tobacco products once categorized as medical devices. Under the terms of the statute, medical device firms must comply with a number of regulatory requirements governing product manufacturing and premarket clearance, many of which are not fully discussed in the preamble. Conversely, once subject to such requirements, device manufacturers may benefit from a powerful federal preemption defense to personal injury lawsuits.

A. *Compliance with Generally Applicable Device Requirements*

1. *Adulteration and Misbranding Prohibitions.*—At the outset, all device manufacturers must comply with a number of ongoing requirements. For example, once classified as medical devices, the statute's basic adulteration and misbranding prohibitions would become fully applicable to tobacco products.¹⁵⁶ In

Violence Study Funds, ATLANTA J. CONST., July 12, 1996, at 6A (describing congressional criticism of the CDC's collection of data on deaths attributable to guns). Even so, any FDA initiatives in areas such as these would seem frivolous. With respect to handguns, for example, its own prior construction of the statutory definition would pose a serious but perhaps not insurmountable problem for the Agency, especially if it does not expect that it will ever have to defend its legal position in federal court. See 61 Fed. Reg. 44,619, 44,684-85 (1996) (jurisdictional statement) (disclaiming authority over guns); *Public Sale of Protective Chemical Sprays: Hearing Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 91st Cong. 36-37 (1969) (statement of William W. Goodrich, FDA Chief Counsel) (explaining that products such as guns and mace are not drugs or medical devices even though clearly intended to affect the structure or function of the body); Gamerman, *supra* note 89, at 853 (suggesting a clarification of the definition of medical device to exclude items such as bullet-proof vests and guns, even though this is an area "into which FDA has not yet ventured").

156. See 21 U.S.C. §§ 351-352 (1994); *United States v. Diapulse Corp. of Am.*, 457 F.2d 25, 31 (2d Cir. 1972) (affirming injunction against continued marketing of misbranded devices); *United States v. Torigian Lab., Inc.*, 577 F. Supp. 1514, 1517 (E.D.N.Y.) (upholding criminal conviction for device adulteration and misbranding),

particular, a drug-delivery device can be marketed only for use with an FDA-approved drug. Where an approved device is marketed for use with an unapproved drug, the Agency has declared that the device is misbranded.¹⁵⁷

Under the Act, nicotine is a "new drug," the composition of which is not "generally recognized as safe" (GRAS) and is, therefore, not exempt from drug approval requirements.¹⁵⁸ The new drug definition contains a grandfather clause which provides that non-GRAS drugs previously subject to the 1906 predecessor of the FD&C Act will not be deemed new drugs.¹⁵⁹ This provision would not, however, relieve nicotine of its NDA obligations because the grandfather clause does not apply once a product is relabeled,¹⁶⁰ and tobacco products necessarily would be relabeled under the Agency's medical device designation. Nicotine has been approved only for use in smoking cessation products and is unlikely ever to be approved for use in tobacco products classified as drug-delivery systems.¹⁶¹

aff'd mem., 751 F.2d 373 (2d Cir. 1984).

157. See FDA Regulatory Letter No. 89-HFD-313-26 (Apr. 28, 1989), noted in HUTT & MERRILL, *supra* note 35, at 749 (warning that an approved infusion pump was misbranded because its labeling promoted the pump for various unapproved uses of several approved drug products). Similarly, an approved general purpose medical device (such as a syringe) labeled for use with an unapproved drug (such as heroin) would violate the misbranding prohibitions of the Act.

158. See, e.g., *United States v. 50 Boxes More or Less*, 909 F.2d 24, 26 (1st Cir. 1990); *Tri-Bio Lab., Inc. v. United States*, 836 F.2d 135, 142 (3d Cir. 1987) (holding that the data presented were inadequate to find that an animal drug was generally recognized as safe); *United States v. Articles of Drug*, 826 F.2d 564, 573 (7th Cir. 1987) (holding that certain toothpastes are "new drugs" under the FD&C Act); *United States v. Undetermined Quantities of "Cal-Ban 3000 . . ."*, 776 F. Supp. 249, 256 (E.D.N.C. 1991) (holding that a weight loss product was a "new drug" under the FD&C Act).

159. See 21 U.S.C. § 321(p)(1).

160. See *id.*; see also *United States v. Allan Drug Corp.*, 357 F.2d 713, 719-20 (10th Cir. 1966); F-D-C REPORTS ("The Pink Sheet"), July 4, 1994, at T&G-2 (describing successful enforcement actions against iodinated glycerol, which manufacturers claimed to be exempt from new drug requirements under the grandfather provisions).

161. Perhaps the closest parallel example is methadone, which is intended for use in the treatment of heroin addiction. See *American Pharm. Ass'n v. Weinberger*, 377 F. Supp. 824, 829 n.9 (D.D.C. 1974) ("FDA's discretion under the Act's NDA provisions is limited to either approving or denying NDA's and nowhere is FDA empowered to approve an NDA upon the condition that the drug be distributed only through specified channels."), *aff'd*, 530 F.2d 1054 (D.C. Cir. 1976) (per curiam). The FDA revised its methadone regulations in response to this decision by deleting the

Other requirements include good manufacturing practice (GMP) controls,¹⁶² which are enforced through periodic inspections,¹⁶³ and the reporting of adverse reactions to (or the malfunctioning of) medical devices.¹⁶⁴ Under these regulations, manufacturers must report all information which suggests that a medical device may have caused or contributed to a death or serious injury.¹⁶⁵ The FDA can order a mandatory recall of a medical device, and it can prohibit further marketing if there is a reasonable probability that continued distribution of the device would cause serious adverse health consequences or death.¹⁶⁶ Thus, unless specifically exempted, tobacco manufacturers will have to submit an adverse reaction report each time a product-related injury occurs. In the final tobacco regulations, the FDA has required that manufacturers submit reports only of unexpected adverse events and instances of contamination or changes in the manufacturing process.¹⁶⁷

restrictions on methadone distribution to pharmacies. *See* 41 Fed. Reg. 28,261 (1976). Unlike methadone, however, nicotine does not treat any medical condition unless it is used in a smoking cessation product to reduce withdrawal symptoms.

162. *See* 21 U.S.C. § 360i; 21 C.F.R. pt. 820 (1996); *see also* 61 Fed. Reg. 44,396, 44,411 (1996).

163. *See, e.g., In re Establishment Inspection of Medtronic, Inc.*, 500 F. Supp. 536, 538-40 (D. Minn. 1980). The Agency regularly takes enforcement action against medical device manufacturers for GMP violations. *See, e.g., United States v. Laerdal Mfg. Corp.*, 853 F. Supp. 1219, 1222-23, 1227-35 (D. Or. 1994), *aff'd*, 73 F.3d 852 (9th Cir. 1995); *United States v. Barr Lab., Inc.*, 812 F. Supp. 458, 465 (D.N.J. 1993); *United States v. Undetermined Quantities of Various Articles*, 800 F. Supp. 499, 502-03 (S.D. Tex. 1992); *United States v. 789 Cases . . . Surgeons' Gloves*, 799 F. Supp. 1275, 1287-93 (D.P.R. 1992).

164. *See* 21 C.F.R. pt. 803.

165. The regulations require a report whenever a device manufacturer becomes aware of information "[i]n the medical or scientific literature, whether published or unpublished, that reasonably suggests that one of its marketed devices (A) may have caused or contributed to a death or serious injury." 21 C.F.R. § 803.24(a)(2)(i). The regulation requires that device manufacturers report the adverse event by telephone within five calendar days of its occurrence, followed up by a written report within 15 working days. *See id.* § 803.24(b)(1).

166. *See* 21 U.S.C. §§ 360e(e), 360h(e). Criminal penalties also may be imposed for failures to abide by the PMA requirements. *See, e.g., United States v. C.R. Bard, Inc.*, 848 F. Supp. 287, 293 (D. Mass. 1994) (approving plea agreement imposing fines totalling more than \$62 million).

167. *See* 21 C.F.R. § 803.19(f). User facilities are entirely exempt, *see id.* § 803.19(g), and distributors only need to report contamination, *see id.* § 804.25(c); *see also* 61 Fed. Reg. at 44,410-11. The FDA estimates that it will receive approximately fifty such reports per year. *See* 61 Fed. Reg. at 44,612. One manufacturer

The Agency notes the existence of most of these generally applicable medical device requirements;¹⁶⁸ however, the preamble accompanying the final regulations provides few details about the consequences of applying these provisions. Instead, the FDA focuses on the “special” requirements it will apply to tobacco products. The Agency may be hoping to finesse the issue and avoid actually applying these other provisions,¹⁶⁹ but the regulations do not specifically exempt tobacco products from many of these medical device requirements, nor is it clear that the FDA even has the authority to permit such an exclusion.¹⁷⁰

2. *Classification and Approval for Marketing.*—In addition to these general controls, all medical devices must be classified by the FDA.¹⁷¹ In classifying a device, the FDA must consider the persons for whose use the device is intended, the conditions of intended use, and it must “weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.”¹⁷² Under this classification

recently recalled billions of cigarettes because of possible chemical contamination. *See Inquiry Sees Nothing Unusual in Batch of Recalled Cigarettes*, N.Y. TIMES, Mar. 29, 1996, at A9.

168. *See* 61 Fed. Reg. at 44,404, 44,409-11, 44,540 (noting that tobacco product manufacturers will have “to comply with the existing device registration and listing requirements,” but that distributors are exempt); 60 Fed. Reg. 41,314, 41,352 (1995) (conceding that, “[a]s devices, the products would also be subject to various pre-existing requirements in the statute and regulations,” including general labeling requirements for devices, establishment registration and device listing requirements, and good manufacturing practice requirements).

169. *See* 61 Fed. Reg. at 44,404 (“Although FDA intends to impose on cigarettes and smokeless tobacco all requirements applicable to devices, the act does not provide that these requirements should all be imposed immediately.”).

170. *See infra* notes 186-190 and accompanying text; *cf.* 21 U.S.C. § 336 (authorizing the FDA to ignore minor statutory violations); *Monsanto Co. v. Kennedy*, 613 F.2d 947, 954-55 (D.C. Cir. 1979) (finding that FDA enjoyed inherent discretion to apply a de minimis exception); *United States v. 449 Cases, Containing Tomato Paste*, 212 F.2d 567, 575 (2d Cir. 1954); *United States v. General Foods Corp.*, 446 F. Supp. 740, 746 (N.D.N.Y. 1978).

171. *See* 21 U.S.C. § 360c(a)(1)(C); 21 C.F.R. pt. 860; *see also* *General Medical Co. v. FDA*, 770 F.2d 214, 216-17 (D.C. Cir. 1985) (summarizing classification procedure); *Contact Lens Mfrs. Ass’n v. FDA*, 766 F.2d 592, 599-603 (D.C. Cir. 1985) (same); *Hearings Before the Sen. Comm. on Labor and Human Resources*, 101st Cong. 1 (1990) (describing the Medical Device Amendments’ (MDA) “three-tiered scheme that regulated medical devices according to their risk”).

172. 21 U.S.C. § 360c(a)(2).

system, tobacco products would fall into Class III as extremely hazardous devices.¹⁷³

Second, manufacturers of medical devices must obtain some sort of premarket clearance for their products. When it recently announced plans to introduce a smokeless cigarette, one company expressed concerns that the FDA would demand that the product undergo a protracted premarket review procedure.¹⁷⁴ Premarket approval (PMA) represents the most rigorous clearance requirement and eventually will be required for all Class III medical devices.¹⁷⁵ The PMA is essentially a product license which imposes precise conditions governing the manufacture and labeling of a device and from which no deviation is permitted.¹⁷⁶ Under the PMA provisions, all devices must be tested for safety and effectiveness, usually under an investigational device exemption (IDE).¹⁷⁷ The PMA application must contain, among other things, a description of the device and its principles of operation, manufacturing methods and controls, labeling and directions for use, and detailed test data, including clinical data from controlled studies in humans, demonstrating the product's safety and effectiveness.¹⁷⁸ When the FDA issues a PMA, it has decided that the device is safe and effective (and

173. See *id.* § 360c(a)(1)(C)(ii)(II) (requiring a Class III designation for devices which "present[] a potential unreasonable risk of illness or injury"); see also 61 Fed. Reg. at 44,411-13 (conceding that tobacco products eventually will be classified but suggesting that it might avoid a Class III designation by taking into account the negative public health consequences of a prohibition). In 1977 and 1978, a public interest group filed citizen petitions requesting that the FDA assert jurisdiction over attached and detached cigarette filters as medical devices, based on a recommendation by an advisory committee that they be classified as Class III devices. See HUTT & MERRILL, *supra* note 35, at 384. The Agency refused to regulate either type of cigarette filter as a medical device absent any therapeutic labeling claims. See 47 Fed. Reg. 31,130, 31,132 (1982); see also *Study Hints of Lung Danger in Cigarettes*, N.Y. TIMES, Jan. 14, 1995, at A12 (reporting on a recent study which revealed that pieces of cigarette filters break off during use and become lodged in the lungs).

174. See Feder, *supra* note 36, at A7.

175. See 21 U.S.C. § 360c(a)(1)(C)(ii)(II); 21 C.F.R. § 814.1(c); see also *United States v. Various Articles of Device . . .*, 814 F. Supp. 32, 33 (E.D. Tenn. 1992).

176. See 21 U.S.C. §§ 351(f)(1), 360e; 21 C.F.R. § 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."); *Ethicon, Inc. v. FDA*, 762 F. Supp. 382, 384 n.2 (D.D.C. 1991) ("Pre-market approval involves the most rigorous review of devices under the Act.").

177. See 21 U.S.C. § 360j(g); 21 C.F.R. § 812.

178. See 21 U.S.C. § 360e(c); 21 C.F.R. § 814.

not adulterated or misbranded) as long as it complies with the conditions specified in the application.

Even if the Agency regarded tobacco products as "grandfathered" Class III devices temporarily exempt from PMA requirements, § 510(k) of the FD&C Act requires the submission of a premarket notification (PMN).¹⁷⁹ With the exception of certain Class I devices for which the FDA does not require a PMN, and Class III devices for which the Agency requires the submission of PMAs, medical devices may be marketed only if they were introduced before May 28, 1976, or are "substantially equivalent" to a device marketed before that date.¹⁸⁰ A PMN would be required each time a company introduces a new product or design,¹⁸¹ and it must include proposed labeling and an explanation of how the device is substantially equivalent in intended use and technological characteristics to a particular predicate device.¹⁸² The FDA reviews PMN submissions to ensure that the new device is substantially equivalent to an identified predicate device. After a substantial equivalence determination has been made by the FDA, the device may be marketed. If significant changes later are made to the device, either a supplement to the original PMN or a brand new PMN is required.¹⁸³

The 510(k) notification must either contain an adequate

179. See 21 U.S.C. § 360(k); 61 Fed. Reg. 44,396, 44,410, 44,463 (1996).

180. See 21 U.S.C. § 360c(i) (defining "substantially equivalent" as having the same intended uses and the same technological characteristics as the predicate device); 21 C.F.R. § 807.81 (same). If the new device has different technological characteristics, the PMN must contain information, including clinical data, demonstrating that the device is as safe and effective as a legally marketed predicate device. See 21 U.S.C. § 360c(i); see also 21 C.F.R. § 807.100; 57 Fed. Reg. 58,400, 58,403 (1992).

181. See 21 C.F.R. § 807.81(a)(3).

182. See *id.* § 807.87 (detailing required elements of a PMN submission). In the case of a Class II device subject to a performance standard, the manufacturer must demonstrate that the device conforms to any such standard. See 21 U.S.C. § 360d; 21 C.F.R. § 807.87(d). The FDA may establish performance standards "to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360d(a)(1). A performance standard may include provisions regarding construction, ingredients, testing, or measurement of the device's performance, and such a standard may restrict the sale and distribution of the device to the extent permitted in the restricted device provisions of the Act. See *id.* § 360d(a)(2).

183. See 21 C.F.R. § 807.81(a)(3); 42 Fed. Reg. 42,520, 42,522 (1977); *United States v. An Article of Device Consisting of 1,217 Cardboard Boxes*, 607 F. Supp. 990, 996-97 (W.D. Mich. 1985); see also 61 Fed. Reg. 44,396, 44,612 (1996) (estimating that there are presently 1,000 varieties of tobacco products on the market).

summary of any information concerning safety and effectiveness, including adverse health effects, or state that such information will be made available to any person upon request.¹⁸⁴ When the Agency receives a PMN that it regards as incomplete, it may request additional information. The failure to include adequate evidence of safety and effectiveness may result in a finding that a device is not "substantially equivalent" to a predicate device. In addition, the Agency has demanded that manufacturers provide clinical data to support their claims that any technological changes did not impact safety and effectiveness.¹⁸⁵

In partial recognition of these hurdles, the FDA noted in its proposal that "on occasion the agency has chosen not to use premarket approval for critical devices that potentially raise significant safety and efficacy issues" even though approval provides the greatest regulatory control,¹⁸⁶ adding that agencies enjoy significant discretion in enforcement matters, as recognized by the Supreme Court in *Heckler v. Chaney*.¹⁸⁷ Although the Court in that case upheld the FDA's decision not to enforce premarket approval requirements for lethal injection drugs,¹⁸⁸ that situation is not analogous to the regulation of tobacco products as medical devices. The decision in *Chaney*

184. 21 U.S.C. § 360c(1)(A)(ii)(I), (3)(A); 21 C.F.R. § 807.93.

185. See H.R. REP. NO. 101-808, at 25 (1990); Richard M. Cooper, *Clinical Data under Section 501(k)*, 42 FOOD DRUG COSM. L.J. 192 (1987); Ellen J. Flannery, *The Safe Medical Devices Act of 1990: An Overview*, 46 FOOD DRUG COSM. L.J. 129, 131 (1991).

186. See 60 Fed. Reg. 41,314, 41,349 (1995) (stating that premarket approval is generally regarded as providing the greatest regulatory control, but that other regulations would be more appropriate). As further precedent, the FDA points to its recent announcement that it will no longer enforce PMA requirements for heart valve allografts. See *id.* (citing 59 Fed. Reg. 52,078 (1994)). In fact, the Agency had little choice in the matter. See *Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522, 536 (7th Cir. 1993) (remanding to district court to determine whether FDA gave adequate notice to heart valve allograft distributors that these products were included in a rule subjecting replacement heart valves to PMA requirements); *Alabama Tissue Ctr. v. Sullivan*, 975 F.2d 373, 379 (7th Cir. 1992) (including heart valve allografts in definition of biologic valves under FDA rule). The Agency subsequently withdrew the rule applying PMA requirements to valve allografts. See 59 Fed. Reg. 52,078 (1994). Wholly apart from judicial compulsion, it is difficult to see how the FDA can view an action relaxing regulatory controls on a dangerous but medically useful product as analogous to its proposal to regulate tobacco products (which have no medical benefits) under the "flexible" medical device provisions.

187. 470 U.S. 821 (1985).

188. See *Heckler*, 470 U.S. at 837.

applies when the Agency imposes statutory requirements on a product but then, in its discretion, chooses not to enforce these requirements. In the case of tobacco products, however, the FDA apparently intends to decline imposing certain mandatory device requirements on tobacco products at the outset.¹⁸⁹ The Agency cannot forever ignore Congress' statutory directives.¹⁹⁰

3. *Disclosure of Trade Secret Information.*—The application of these various medical device requirements to tobacco products also may result in the disclosure of information currently protected as trade secrets. Pursuant to the cigarette labeling statute, manufacturers must submit annual ingredient lists to HHS, but the lists need not specifically identify the company or the brand of cigarettes.¹⁹¹ All information submitted under the statute is considered trade secret information,¹⁹² and federal

189. See 61 Fed. Reg. 44,396, 44,416 (1996). The statute requires, for example, that "the Secretary *shall* classify all such devices . . . into the classes" established by the Act. 21 U.S.C. § 360c(b)(1) (1994) (emphasis added); see also *id.* §§ 360(k) (premarket notification requirement), 360i(a) (adverse event reporting). Where the statute is not drawn in mandatory terms, of course, the FDA is free to exempt certain devices from general controls. See 60 Fed. Reg. 59,557, 59,560 (1995) (describing recent exemptions of several low-risk devices from such general controls); cf. *Doe v. Sullivan*, 938 F.2d 1370, 1382 (D.C. Cir. 1991) (upholding FDA regulation exempting biowarfare vaccines from IND requirements under certain limited circumstances); Jeffrey M. Sellers, Note, *Regulatory Values and the Exceptions Process*, 93 YALE L.J. 938, 957 (1984).

190. See, e.g., *Cutler v. Hayes*, 818 F.2d 879, 895 (D.C. Cir. 1987) ("Although FDA's discretion extends to review of OTC drugs by ingredient rather than by product . . . the agency lacks authority to simply do nothing to effectuate the purpose of the Act."); *Cutler v. Kennedy*, 475 F. Supp. 838, 854 (D.D.C. 1979) ("The Commissioner's OTC regulations formally authorize the continued marketing of Category III drug products in the absence of an administrative determination that those products are, today, generally recognized by experts as safe and effective. That flies in the face of the statutory scheme."); *id.* at 856 ("FDA may not lawfully maintain Category III in any form in which drugs with Category III conditions . . . are exempted from enforcement action. Informally, of course, the FDA will be free to exercise its discretion . . . not to seek enforcement actions."); see also Ronald M. Levin, *Understanding Unreviewability in Administrative Law*, 74 MINN. L. REV. 689, 753-79 (1990) (canvassing various limitations on an agency's discretion not to act).

191. See 15 U.S.C. § 1335a(a) (1994); see also Mark A. Rothstein, *Refusing to Employ Smokers: Good Public Health or Bad Public Policy?*, 62 NOTRE DAME L. REV. 940, 943 (1987) ("Tobacco smoke contains between three thousand and four thousand chemicals, more than twenty of which have been shown to cause cancer or tumors."). No reports on other tobacco products or on tobacco injuries or deaths are required.

192. See 15 U.S.C. § 1335a(b)(2)(A).

officials cannot disclose any of the ingredients except to Congress.¹⁹³

At least two of the generally applicable medical device regulations arguably would require that manufacturers of tobacco products disclose ingredient information. First, a PMN submission requires specification of the "material[s] used" in the device.¹⁹⁴ Second, GMP controls require that manufacturers maintain a "device master record" available to inspectors which must contain the device's "formulation" and information about components.¹⁹⁵ Both of these regulations provide that the required information will be kept confidential only to the extent authorized by the Freedom of Information Act (FOIA).¹⁹⁶ The FDA's implementing regulations define trade secrets as "information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs."¹⁹⁷ Because tobacco companies regularly submit ingre-

193. The Secretary of HHS is empowered to report to Congress any research findings or other information which suggest that one or more of the listed ingredients poses a health risk to smokers. *See id.* § 1335a(b)(1); *see also* Barbara Carton, *Tobacco: State Demands List of Contents for Cigarettes*, WALL ST. J., Aug. 2, 1996, at B1 (describing passage of ingredient disclosure law in Massachusetts and tobacco industry plans to challenge it as inconsistent with trade secret protection under federal law).

194. *See* 21 C.F.R. § 807.92(a)(4) (1996) (requiring a description of the device, "including an explanation of how the device functions" and "the significant physical . . . characteristics of the device, such as device design [and] material[s] used"). It should be noted, however, that these requirements "have been modified to reflect the agency's intention that trade secret and confidential commercial information be protected." 59 Fed. Reg. 64,287, 64,289 (1994) (adding that the 510(k) summary should be provided "in a form that is clear, concise, and adequate, but not so detailed as to disclose trade secret information").

195. *See* 21 C.F.R. § 820.181(a); 61 Fed. Reg. 44,396, 44,540-41 (1996) (explaining the scope of the FDA's authority to inspect records); *see also id.* at 44,463-64 (discussing the inapplicability of trade secret protection but declining to impose ingredient labeling requirements).

196. *See* 5 U.S.C. § 552(b)(4) (1994); *see also* 21 C.F.R. § 20.61(c) (providing that data and information submitted to the FDA which fall within definitions of trade secret or confidential commercial information are not available for public disclosure under FOIA); *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 877-78 (D.C. Cir. 1992) (en banc). FOIA also exempts from disclosure other information if a different statute requires that it be withheld from the public. *See* 5 U.S.C. § 552(b)(3). The cigarette labeling statute, however, only prohibits the disclosure of ingredient information submitted to HHS under that particular reporting requirement. *See* 15 U.S.C. § 1335a(b)(2)(A) (1994).

197. 21 C.F.R. § 20.61(b); *see also* *Public Citizen Health Research Group v. FDA*,

dient information to their trade association, it may be difficult to argue that this data qualifies for trade secret protection. Thus, if generally applicable medical device provisions will apply to tobacco products under the new FDA regulations, then the effect may be to circumvent the special trade secret provisions currently applicable to ingredient lists.

* * * * *

At this juncture, the FDA has not been fully candid about the possible consequences of applying all of these medical device requirements to cigarettes. If the Agency decides that tobacco product manufacturers need to comply with only a small subset of the requirements applicable to all other devices, public interest groups undoubtedly will challenge the failure to enforce those other requirements.¹⁹⁸ Moreover, even if the Agency were properly exercising its discretion by not enforcing the other provisions of the statute, the tobacco industry has no assurances that this policy would continue; absent an exemption formalized in the final rule, the FDA could easily change its mind and bring enforcement actions at a later date. The Agency's assertion of jurisdiction over cigarettes as medical devices logically carries with it the application of all medical device regulatory requirements to manufacturers of tobacco products.

B. The Preemption Dimension

Perhaps the most alarming possible consequence of the Agency's decision to regulate tobacco products using its authority over medical devices is the added protection against tort lia-

704 F.2d 1280, 1290-91 (D.C. Cir. 1983) (holding that commercial information could be given confidentiality if its disclosure would "cause substantial harm to the competitive position of the person from whom the information was obtained").

198. Cf. *Action on Smoking & Health v. Harris*, 655 F.2d 236, 243 (D.C. Cir. 1980) (upholding the FDA's rejection of a public interest group's citizen petition requesting that cigarettes be regulated as drugs); *Public Citizen v. Commissioner of FDA*, 724 F. Supp. 1013, 1019-20 (D.D.C. 1989) (ordering the FDA to promulgate tampon absorbency labeling regulations within two months, and criticizing the FDA's seven-year delay in issuing these regulations); *Public Citizen v. Heckler*, 653 F. Supp. 1229, 1241 (D.D.C. 1986) (granting petition for review where the FDA had rejected requests that it regulate raw milk).

bility that this may give manufacturers. Unlike most other industries subject to FDA regulation, device manufacturers currently benefit from a statutory provision expressly preempting nonidentical state requirements.¹⁹⁹ Almost without exception, lower courts have held that this provision preempts tort claims to the extent that the FDA regulates a particular device,²⁰⁰ and the Supreme Court's latest decision on this question simply demands that the Agency requirement be specific to the device in question.²⁰¹ By contrast, cigarette manufacturers heretofore have enjoyed a substantially more limited preemption defense against products liability claims.

1. The Existing Defense Against Failure-to-Warn Claims.—Since 1965, Congress has prescribed the warnings that must appear on the labels of cigarette packages.²⁰² At present, cigarette manufacturers are protected from inconsistent state labeling regulations so long as they comply with the federal warning statute.²⁰³ In *Cipollone v. Liggett Group, Inc.*,²⁰⁴ the Su-

199. The statute provides in relevant part as follows:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (1994). This provision was part of the MDA enacted in 1976. See Pub. L. No. 94-295, § 2, 90 Stat. 540, 574. A limited class of FDA food labeling requirements also expressly preempt state law. See 21 U.S.C. § 343-1(a).

200. See Lars Noah, *Amplification of Federal Preemption in Medical Device Cases*, 49 FOOD & DRUG L.J. 183, 199-200 (1994). A number of courts have found that no claims are preempted because a particular device is not regulated by FDA. See, e.g., *Anguiano v. E.I. Du Pont de Nemours & Co.*, 44 F.3d 806, 810 (9th Cir. 1995); *Oliver v. Johnson & Johnson, Inc.*, 863 F. Supp. 251, 253-55 (W.D. Pa. 1994). Only a few have held that tort claims are never preempted. See, e.g., *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1458-59 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 2579 (1996); *Haudrich v. Howmedica, Inc.*, 642 N.E.2d 206, 215 (Ill. App. 1994), *aff'd*, 662 N.E.2d 1248 (Ill. 1996); see also Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 916-42 (1994) (criticizing trend toward finding express preemption of common law claims).

201. See *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2255-58 (1996). Four members of the Court suggested that the MDA does not preempt any tort claims. See *id.* at 2251-53, 2259 (plurality).

202. See *supra* Part II.A.2.

203. See 15 U.S.C. § 1334(b) (1994) ("No requirement or prohibition based on

preme Court held that this statute also expressly preempts products liability actions grounded on failure-to-warn (but not other) claims, even though the provision did not explicitly delineate any such claims as subject to preemption.²⁰⁵ Justice Stevens, writing for himself and three other members of the Court on this question, focused on the breadth of the statutory phrase "requirement or prohibition," concluding that it "sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules."²⁰⁶

Justice Stevens proceeded to evaluate each of plaintiff's claims to determine whether it was preempted. First, he found preemption of the failure-to-warn claim.²⁰⁷ The plaintiff's ex-

smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter."); see also *Vango Media, Inc. v. City of New York*, 34 F.3d 68, 75 (2d Cir. 1994) (holding that city ordinance mandating certain warnings in cigarette advertisements was preempted by federal law).

204. 505 U.S. 504 (1992) (plurality).

205. See *Cipollone*, 505 U.S. at 525-29 (Stevens, J., joined by Rehnquist, C.J., White, and O'Connor, JJ.) (concluding that breach of express warranty and certain fraudulent misrepresentation claims were not preempted). Two other Justices found an even broader preemptive effect in the statute and would have held all common law claims preempted under the 1969 amendment. See *id.* at 544-56 (Scalia, J., joined by Thomas, J., concurring in part and dissenting in part). The remaining three Justices would have held none of the claims preempted. See *id.* at 534-44 (Blackmun, J., joined by Kennedy and Souter, JJ., concurring in part and dissenting in part). Because the Court was fragmented on the preemptive force of the 1969 provision, "and no single rationale explaining the result enjoy[ed] the assent of five Justices," the holding may be viewed as the position taken by those concurring on the narrowest grounds. See *Marks v. United States*, 430 U.S. 188, 193 (1977); see also *Nichols v. United States*, 114 S. Ct. 1921, 1926 (1994) ("This test is more easily stated than applied to the various opinions supporting the result in" a particular case.).

206. *Cipollone*, 505 U.S. at 521-22 (Stevens, J., joined by Rehnquist, C.J., White, and O'Connor, JJ.) ("[C]ommon-law damages actions of the sort raised by petitioner are premised on the existence of a legal duty, and it is difficult to say that such actions do not impose 'requirements or prohibitions.'"); see also *CSX Transp., Inc. v. Easterwood*, 113 S. Ct. 1732, 1737 (1993).

207. See *Cipollone*, 505 U.S. at 524-25. The Court stated that:

Thus, insofar as claims under either failure-to-warn theory require a showing that respondents' post-1969 advertising or promotions should have included additional, or more clearly stated, warnings, those claims are pre-empted. The Act does not, however, pre-empt petitioner's claims that rely solely on respondents' testing or research practices or other actions unrelated to advertising or promotion.

press warranty claim was not, however, preempted because the imposition of liability would arise from the breach of "a contractual commitment voluntarily undertaken" by the warrantor rather than from a violation of any requirement imposed under state law.²⁰⁸ Justice Stevens then subdivided plaintiff's fraudulent misrepresentation claim into two distinct theories: one alleging that the companies' advertising neutralized the effect of the warnings mandated by Congress, a claim which was preempted just as the failure-to-warn claim,²⁰⁹ and one alleging violations of a more general duty not to conceal material facts, a claim which was not preempted "insofar as those claims rely on a state law duty to disclose such facts through channels of communication other than advertising or promotion."²¹⁰

Thus, *Cipollone* only preempts a limited subset of tort claims involving cigarettes. For instance, Justice Stevens noted that the statute would not preempt claims alleging defects in manufacturing or product design.²¹¹ In addition, plaintiffs suing cigarette manufacturers have managed to elude *Cipollone* by recasting inadequate warning claims as, for example, fraud or breach of express warranty.²¹² Finally, *Cipollone* provides no

Id.

208. *See id.* at 526. "[A] contractual requirement, although only enforceable under state law, is not 'imposed' by the State, but rather is 'imposed' by the contracting party upon itself." *Id.* at 526 n.24; *see also* *American Airlines, Inc. v. Wolens*, 115 S. Ct. 817, 824-26 (1995) (holding that Airline Deregulation Act did not preempt breach of contract claims involving frequent flyer program).

209. *Cipollone*, 505 U.S. at 527-28 ("Such a claim is predicated on a state-law prohibition against statements in advertising and promotional materials that tend to minimize the health hazards associated with smoking."). "In this light it seems quite clear that petitioner's first theory of fraudulent misrepresentation is inextricably related to petitioner's first failure-to-warn theory, a theory that we have already concluded is largely pre-empted by § 5(b)." *Id.* at 528.

210. *Id.* "State-law prohibitions on false statements of material fact do not create 'diverse, nonuniform, and confusing' standards. Unlike state law obligations concerning the warning necessary to render a product 'reasonably safe,' state-law proscriptions on intentional fraud rely only on a single, uniform standard: falsity." *Id.* at 529. Similarly, Justice Stevens took the position that the plaintiff's conspiracy to commit such fraud was not preempted. *See id.* at 530.

211. *See id.* at 523.

212. *See, e.g.,* *Castano v. American Tobacco Co.*, 870 F. Supp. 1425, 1432-34 (E.D. La. 1994) (rejecting preemption defense against fraud and deceit, negligent misrepresentation, intentional infliction of emotional distress, violation of consumer protection statutes, breach of express and implied warranties, negligent manufacturing and design, and strict liability claims); *Grinnell v. American Tobacco Co.*, 883 S.W.2d

defense for manufacturers of smokeless tobacco products.²¹³

2. *Broader Preemption for Device Manufacturers.*—Both before and after *Cipollone*, express preemption as a defense to tort liability has arisen most frequently in products liability litigation against manufacturers of medical devices. Congress expressed an even broader intent to preempt state laws applicable to medical devices than the provision at issue in *Cipollone*. The 1969 legislation only preempted requirements or prohibitions related to the promotion of cigarettes.²¹⁴ By comparison, the MDA preempts any state medical device requirement which is different from or in addition to an applicable FDA requirement and “which relates to” either the safety or effectiveness of the device or “any other matter included in a requirement applicable to the device under this chapter.”²¹⁵

For instance, courts have dismissed claims against tampon manufacturers for failure to warn of toxic shock syndrome because the FDA imposes specific warning requirements for these products.²¹⁶ More recent preemption decisions involving medical devices are even more sweeping, holding that premarket approval by the Agency defeats a variety of common law claims including those alleging defective design, testing, manufacture, or labeling.²¹⁷ Courts have been only slightly more hesitant to

791, 797-98 (Tex. App. 1994) (same); cf. *Mangini v. R.J. Reynolds Tobacco Co.*, 875 P.2d 73, 80-83 (Cal.) (holding that claim for violation of state consumer protection statute was not preempted), *cert. denied*, 115 S. Ct. 577 (1994); *Kyte v. Philip Morris, Inc.*, 556 N.E.2d 1025, 1030 (Mass. 1990) (rejecting preemption defense to claims by minors addicted to cigarettes alleging breach of implied warranty and violation of state consumer protection statute).

213. The Comprehensive Smokeless Tobacco Health Education Act preempts only state statutes or regulations. See 15 U.S.C. § 4406(b), (c) (1994) (“Nothing in this chapter shall relieve any person from liability at common law or under State statutory law to any other person.”); see also *Marsee v. United States Tobacco Co.*, 639 F. Supp. 466 (W.D. Okla. 1986) (describing products liability claims brought against the manufacturer of a smokeless tobacco product), *aff’d*, 866 F.2d 319 (10th Cir. 1989).

214. See *Cipollone*, 505 U.S. at 530-31.

215. See 21 U.S.C. § 360k(a) (1994); see also *Noah*, *supra* note 200, at 184-88.

216. See *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 990-92 (8th Cir. 1994); *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246-47 (5th Cir. 1989).

217. See, e.g., *Mitchell v. Collagen Corp.*, 67 F.3d 1268, 1280-81 (7th Cir. 1995) (injectable collagen), *vacated*, 116 S. Ct. 2576 (1996); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324-31 (3d Cir.) (artificial heart valve), *cert. denied*, 116 S. Ct. 67 (1995);

find preemption of tort claims against manufacturers of devices distributed without full premarket approval, such as those being used in clinical trials pursuant to the FDA's investigational device exemption,²¹⁸ or devices cleared for marketing under § 510(k) as substantially equivalent to an existing product,²¹⁹ though the Supreme Court has now significantly restricted the scope of preemption in the latter situation.²²⁰

Although no court has suggested that federal law preempts all tort claims against all devices, there is a growing consensus that such claims are preempted to the extent that the FDA regulates a particular device, whether through published regulations or the individualized review and approval of applications to market a medical device. These decisions are more expansive than *Cipollone*. For instance, a few courts have held that breach of express warranty claims are preempted.²²¹ Indeed, a number of lower courts have found sweeping preemption of tort claims even in instances where the manufacturer has failed to comply

Martello v. CIBA Vision Corp., 42 F.3d 1167, 1169 (8th Cir. 1994) (contact lens solution), *cert. denied*, 115 S. Ct. 2614 (1995); King v. Collagen Corp., 983 F.2d 1130, 1133-36 (1st Cir. 1993) (injectable collagen); Stamps v. Collagen Corp., 984 F.2d 1416, 1421-25 (5th Cir. 1993) (injectable collagen). *But see* Kennedy v. Collagen Corp., 67 F.3d 1453, 1458-59 (9th Cir. 1995) (holding that the MDA never preempts tort claims, refusing to follow the consensus position of the other circuits), *cert. denied*, 116 S. Ct. 2579 (1996).

218. *See, e.g.*, Martin v. Teletronics Pacing Sys., Inc., 70 F.3d 39, 41-42 (6th Cir. 1995) (pacemaker), *vacated*, 116 S. Ct. 2576 (1996); Becker v. Optical Radiation Corp., 66 F.3d 18, 20-21 (2d Cir. 1995) (intraocular lenses); Gile v. Optical Radiation Corp., 22 F.3d 540, 541-42 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); Duncan v. IOLAB Corp., 12 F.3d 194 (11th Cir. 1994) (*per curiam*); Slater v. Optical Radiation Corp., 961 F.2d 1330, 1333 (7th Cir. 1992); Hunsaker v. Surgidev Corp., 818 F. Supp. 744, 753 (M.D. Pa. 1992), *affd mem.*, 5 F.3d 1489 (3d Cir. 1993).

219. *See, e.g.*, English v. Mentor Corp., 67 F.3d 477, 481-83 (3d Cir. 1995) (penile prosthesis), *vacated*, 116 S. Ct. 2575 (1996); Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392, 398-401 (4th Cir. 1995) (penile prosthesis), *vacated*, 116 S. Ct. 2575 (1996); Reeves v. AcroMed Corp., 44 F.3d 300, 305-07 (5th Cir.) (metal bone plate and screws), *cert. denied*, 115 S. Ct. 2251 (1995); Mendes v. Medtronic, Inc., 18 F.3d 13, 17-19 (1st Cir. 1994) (pacemaker); *cf.* Feldt v. Mentor Corp., 61 F.3d 431, 436-38 (5th Cir. 1995) (premarket clearance would preempt warning and manufacturing but not design defect claims), *vacated*, 116 S. Ct. 2575 (1996).

220. *See* Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2255-58 (1996) (holding that none of the products liability claims against a pacemaker manufacturer were preempted because the generic premarket notification, good manufacturing practice, and labeling regulations did not impose any specific FDA requirements on the device).

221. *See* Martin, 70 F.3d at 42; Duvall, 65 F.3d at 400-01; Martello, 42 F.3d at 1169; King, 983 F.2d at 1135-36. *But see* Mitchell, 67 F.3d at 1285.

with FDA requirements.²²²

The FDA's new advertising and labeling restrictions might preempt failure-to-warn and related claims against manufacturers of both cigarettes and smokeless tobacco products. If tobacco companies file premarket notifications in the future, courts may hold that certain design defect and other labeling claims are preempted, notwithstanding the *Medtronic* decision.²²³ Even the specific application of medical device GMP requirements to tobacco products could preempt manufacturing defect claims.²²⁴

The FDA surely does not intend to protect manufacturers in this manner.²²⁵ Indeed, the Agency has previously expressed its disagreement with any preemption of tort claims against device manufacturers,²²⁶ but it has not yet persuaded the courts. The tobacco industry may or may not recognize the potential benefits of a medical device approach to regulation, but it certainly has not broached the subject in public.²²⁷

222. See, e.g., *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 30-31 (1st Cir. 1995), *cert. dismissed*, 116 S. Ct. 1892 (1996); *Michael*, 46 F.3d at 1328-29; *Reeves*, 44 F.3d at 307. For an argument that these courts have seriously misinterpreted *Cipollone* in this respect, see Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 WM. & MARY L. REV. 903 (1996). The Supreme Court recently suggested that the defense would not apply in such circumstances. See *Medtronic*, 116 S. Ct. at 2255; *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part).

223. See Lars Noah, *The Pre-emption Morass*, LEGAL TIMES, July 29, 1996, at S37 (explaining the limited scope of the plurality's decision); Noah, *supra* note 200, at 208-10 (suggesting meaningful differences in the PMN review process before and after 1990).

224. See *Duwall*, 65 F.3d at 399; *Mendes*, 18 F.3d at 19 (holding that "plaintiff's negligent manufacturing claim (including her allegations of negligent manufacturing, control, maintenance, inspection, testing, servicing, distribution, and sale of the device) is preempted by FDA regulations on good manufacturing practices").

225. See 61 Fed. Reg. 44,396, 44,550 (1996) ("FDA does not expect any of these Federal requirements to preempt any tort claims relating to tobacco products.").

226. In one recent appeal, the Department of Justice filed an *amicus curiae* brief, explaining the FDA's opposition to preemption in this case. See Brief for the United States as Amicus Curiae, *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995) (No. 94-1951), *noted in* 22 Prod. Safety & Liab. Rep. (BNA) 1230 (1994). Indeed, as suggested in the brief, the Agency does not believe that the MDA ever preempts common law claims. *Id.* at 14 n.5; see also *Duwall*, 65 F.3d at 401 n.9. Although courts will defer to agency interpretations against statutory preemption, see *American Airlines, Inc. v. Wolens*, 115 S. Ct. 817, 821-22, 824-25 (1995), the FDA cannot quite so easily disavow in litigation papers what appears to be a formal and long-standing construction of the statute, see *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212-13 (1988).

227. Cf. *Product Liability Standards: Hearings Before the Subcomm. on Com-*

IV. CONSTITUTIONAL OBJECTIONS TO THE REGULATIONS

The industry already has filed lawsuits challenging the proposed restrictions as inconsistent with both the statute and the First Amendment.²²⁸ In seeking to prevent tobacco companies from encouraging illegal tobacco use by minors, the FDA's advertising restrictions will affect "commercial speech" significantly. The Agency also proposes to require industry-wide participation in an educational campaign directed at potential and actual underage tobacco users. This aspect of the initiatives will be even more vulnerable to legal challenge under the First Amendment than some of the other advertising and point-of-sale limitations.

In *Central Hudson Gas & Electric Corporation v. Public Service Commission*,²²⁹ the Supreme Court developed a four-part test to determine whether a restriction on commercial speech exceeds First Amendment limitations:

For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.²³⁰

merce, Consumer Protection, and Competitiveness of the House Comm. on Energy and Commerce, 103d Cong. 196 (1994) (statement of William Nealon, Vice President & General Counsel of Telectronics Pacing Systems) (In light of recent preemption decisions, "we firmly believe that tort reform has already arrived for medical device manufacturers.").

228. See *supra* note 20. For the FDA's response to various and sundry other constitutional arguments, including "takings" and due process challenges to the restriction on the use of brand-names, see, e.g., 61 Fed. Reg. 44,396, 44,550-56, 44,428-29 (1996); see also *Warner-Lambert Co. v. FTC*, 562 F.2d 749, 758-59 (D.C. Cir. 1977) (holding that a corrective advertising cease and desist order did not constitute a taking).

229. 447 U.S. 557 (1980).

230. *Central Hudson*, 447 U.S. at 566. The four-part analysis in *Central Hudson* was reaffirmed recently in the Court's decision to overturn a prohibition on the disclosure of alcohol content in the labeling of beer. See *Rubin v. Coors Brewing Co.*, 115 S. Ct. 1585 (1995); see also *44 Liquormart, Inc. v. Rhode Island*, 116 S. Ct. 1495, 1508-10 (1996) (plurality) (striking down state prohibition against alcohol price advertising as unconstitutional under the *Central Hudson* test, and suggesting an even stricter test for scrutinizing such outright prohibitions on commercial speech);

In other words, assuming that the speech does not relate to some unlawful activity and is not inherently misleading, the government may restrict commercial speech only to achieve a substantial interest, and then only to the extent necessary.

A. *Government Interest in Controlling Tobacco Advertising*

The *Central Hudson* test asks first whether the speech in question is false or relates to some illegal activity; if so, it is not protected by the First Amendment and may be banned altogether.²³¹ The government has not suggested that existing labeling and advertising of tobacco products is false, and tobacco companies have refrained from expressly urging underage use. Nonetheless, the FDA could take the position that certain types of tobacco advertising encourage unlawful use or are inherently misleading. Curiously, in defending the constitutionality of its proposed restrictions on tobacco advertising, the FDA did not initially argue that such advertising promotes an unlawful activity or is inherently misleading.²³² In the preamble accompanying the final regulations, the Agency suggested but did not rely upon this argument.²³³

id. at 1522 (O'Connor, J., concurring in judgment) ("Because Rhode Island's regulation fails even the less stringent standard set out in *Central Hudson*, nothing here requires adoption of a new analysis for the evaluation of commercial speech regulation.").

231. See *Central Hudson*, 447 U.S. at 566; see also *United States v. Edge Broad. Co.*, 509 U.S. 418, 426-30 (1993) (upholding a federal statute restricting broadcast advertising of lotteries if unlawful within a state); *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 509 U.S. 418, 426-30 (1982) (rejecting First Amendment challenge to ordinance guidelines which regulate the sale of drug paraphernalia within a certain proximity of any literature encouraging the use of illegal drugs); *Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations*, 413 U.S. 376, 388 (1973) ("We have no doubt that a newspaper constitutionally could be forbidden to publish a want ad proposing a sale of narcotics or soliciting prostitutes.").

232. See 60 Fed. Reg. 41,314, 41,354 (1995) ("The *Central Hudson* analysis begins with the second prong.").

233. See 61 Fed. Reg. at 44,470-72; cf. Vincent Blasi & Henry P. Monaghan, *The First Amendment and Cigarette Advertising*, 256 JAMA 502, 506 (1986) (arguing that cigarette advertising is deceptive and misleading); Kenneth L. Polin, *Argument for the Ban of Tobacco Advertising: A First Amendment Analysis*, 17 HOFSTRA L. REV. 99, 113 (1988) (arguing that tobacco product advertising is inherently misleading and can thus be banned without violating constitutional protections for commercial

Assuming that the commercial speech is neither false nor misleading, the second prong of the *Central Hudson* test asks whether the asserted government interest in enacting the regulation is substantial.²³⁴ The FDA simply notes that it has a significant interest in protecting the public health by reducing smoking among youngsters and proceeds to the third prong of the analysis.²³⁵ The government undoubtedly has a legitimate interest in reducing the number of minors who begin smoking, both to protect the health of those individuals and to reduce the cost to society in caring for them when they suffer from tobacco-related illnesses.²³⁶

B. *The Nexus Between Means and Ends*

Assuming the existence of a substantial government interest, the next question is whether the regulation directly advances the asserted interests.²³⁷ Although the FDA takes comfort in the Supreme Court's willingness in one recent case to accept anecdotal evidence in support of a restriction on commercial speech,²³⁸ the Court generally has been reluctant to allow in-

speech).

234. See *Central Hudson*, 447 U.S. at 566; see also *Posadas de Puerto Rico Assocs. v. Tourism Co. of Puerto Rico*, 478 U.S. 328, 341 (1986) (holding that the legislature's interest in promoting the health, safety, and welfare of its citizens by reducing their demand for gambling is substantial and justifies the regulation of gambling advertising).

235. See 61 Fed. Reg. at 44,472-73.

236. See, e.g., *id.* at 44,399; Jane E. Brody, *Study in Massachusetts Finds That Cigarettes Stunt Lungs of Young Smokers*, N.Y. TIMES, Sept. 26, 1996, at A8. To the extent that the FDA asserts a collateral goal of reducing consumption by adults exposed to the same types of advertising, the proposed restrictions may be harder to justify under the remaining prongs of the *Central Hudson* test. See 44 *Liquormart, Inc. v. Rhode Island*, 116 S. Ct. 1495, 1508 (1996) (plurality) ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good."); see also *id.* at 1516 (Thomas, J., concurring in judgment) (concluding that such an interest is "per se illegitimate").

237. See *Central Hudson*, 447 U.S. at 564 (explaining that "the regulatory technique must be in proportion to that interest" and "must be designed carefully to achieve the State's goal").

238. See 61 Fed. Reg. at 44,474; *Florida Bar v. Went for It, Inc.*, 115 S. Ct. 2371, 2377-78 (1995) ("The anecdotal record mustered by the Bar is noteworthy for its breadth and detail In any event, we do not read our case law to require that empirical data come to us accompanied by a surfeit of background informa-

interference with protected speech on the basis of such tenuous connections.²³⁹ In *Rubin v. Coors Brewing Co.*,²⁴⁰ for example, the Court emphasized that the government shoulders the burden of showing that a restriction advances its asserted interests "in a direct and material way."²⁴¹

The FDA has gathered a wealth of evidence regarding the association between promotion and the use of cigarettes and smokeless tobacco products by minors.²⁴² The Agency also has collected evidence, including reports of success in other countries, to demonstrate that advertising restrictions reduce consumption.²⁴³ Thus, it concludes, the restrictions directly advance the government's legitimate interest in protecting public health.²⁴⁴ The Agency's restrictions on advertising (such as text-only format, the ban on promotional items, and restrictions on sponsorship) seem likely to reduce demand for cigarettes among the adolescent population to some extent,²⁴⁵ though

tion."). The Court was sharply divided on this and other aspects of the case. See *Florida Bar*, 115 S. Ct. at 2384 (Kennedy, J., dissenting) ("Our cases require something more than a few pages of self-serving and unsupported statements by the State to demonstrate that a regulation directly and materially advances the elimination of a real harm when the State seeks to suppress truthful and nondeceptive speech.").

239. See *Central Hudson*, 447 U.S. at 569 (noting that the link between the advertising prohibition and the utility's rate structure was tenuous, even if there was an "immediate connection" between the advertising at issue and the demand for electricity: "[T]he Commission's laudable concern over the equity and efficiency of appellant's rates does not provide a constitutionally adequate reason for restricting protected speech."); see also *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993) (explaining that the government's burden is not satisfied by "mere speculation or conjecture").

240. 115 S. Ct. 1585 (1995).

241. See *Rubin*, 115 S. Ct. at 1592; 44 *Liquormart, Inc.*, 116 S. Ct. at 1509-10 (plurality) (finding inadequate evidence to support the state's claim that its ban on alcohol price advertising would promote temperance).

242. See 61 Fed. Reg. at 44,488-89 (summarizing the evidence); *id.* at 44,466-69, 44,475-88, 44,494-95 (detailing the evidence).

243. See *id.* at 44,489-93.

244. See *id.* at 44,495.

245. See Erica Swecker, Note, *Joe Camel: Will "Old Joe" Survive?*, 36 WM. & MARY L. REV. 1519, 1522-25 (1995); Timothy Noah, *Study Says Minors Respond More to Cigarette Ads Than Do Adults*, WALL ST. J., Apr. 4, 1996, at B8 (summarizing a new study finding that advertising influenced adolescent smokers' preferences among cigarette brands). But see 44 *Liquormart, Inc.*, 116 S. Ct. at 1509-10 (plurality) (discounting the value of evidence concerning the purported link between price advertising and the level of alcohol consumption).

forced reductions in the billions of dollars spent annually by the tobacco industry for advertising could lead to greater price competition, which might increase purchasing by minors.²⁴⁶

Finally, even if the advertising restrictions would be effective in reducing adolescent tobacco use, the regulations seem vulnerable under the final prong of the *Central Hudson* test,²⁴⁷ which requires that a restriction be no more extensive than necessary to achieve the government's goal.²⁴⁸ The preamble includes a detailed explanation to justify each of its advertising limitations.²⁴⁹ Nonetheless, some of the FDA's restrictions fail to differentiate between advertisements directed at minors, in whose welfare the government asserts the substantial interest in this context, and advertisements directed at adults.²⁵⁰ More-

246. See Daniel Helberg, Note, *Butt Out: An Analysis of the FDA's Proposed Restrictions on Cigarette Advertising Under the Commercial Speech Doctrine*, 29 LOY. L.A. L. REV. 1219, 1260 (1996). The FDA dismisses this possibility with little discussion. See 61 Fed. Reg. at 44,511. It concedes elsewhere that the industry will save money but speculates that the unspent advertising budgets will be redirected as increased dividends for shareholders or investments in other product lines. See *id.* at 44,570. Perhaps the money will be absorbed by mounting legal bills.

247. See Helberg, *supra* note 246, at 1258-66; David Cole, *Muzzling Joe Camel*, LEGAL TIMES, May 6, 1996, at 22; cf. Lars Noah & Barbara A. Noah, *Liberating Commercial Speech: Product Labeling Controls and the First Amendment*, 47 FLA. L. REV. 63, 99-104 (1995) (evaluating the FDA's food labeling restrictions on health claims); Rosanna Tainbunni, *Tough Restrictions on Tobacco Ads Struck Down By High Court*, WALL ST. J., Sept. 22, 1995, at B2 (discussing Canadian decision).

248. See, e.g., *City of Cincinnati v. Discovery Network, Inc.*, 113 S. Ct. 1505, 1510 n.13 (1993).

[W]hile we have rejected the "least-restrictive-means" test for judging restrictions on commercial speech, so too have we rejected mere rational basis review [I]f there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech, that is certainly a relevant consideration in determining whether the "fit" between ends and means is reasonable. *In re R.M.J.*, 455 U.S. 191, 203 (1982); see also *Central Hudson*, 447 U.S. at 566.

249. See 61 Fed. Reg. at 44,500-37, 44,610. The FDA repeatedly explains that adults will continue to have access to informational advertising through the text-only format (and to unrestricted advertising in adult publications and establishments) but that children will no longer be exposed to appealing colors and imagery. For an argument that such restrictions violate the Constitution, see Martin H. Redish, *Tobacco Advertising and the First Amendment*, 81 IOWA L. REV. 589, 625-30, 638 (1996). According to Professor Redish, only the restrictions on tobacco advertising in the vicinity of schools or playgrounds pass First Amendment muster. See *id.* at 608.

250. Cf. *Sable Communications v. FCC*, 492 U.S. 115, 131 (1989) (invalidating restriction on phone-sex services that "has the invalid effect of limiting the content of adult telephone conversations to that which is suitable for children to hear"); *Penn Adver., Inc. v. Mayor of Baltimore*, 63 F.3d 1318, 1325-26 (4th Cir. 1995) (rejecting

over, the government should consider less restrictive alternatives, such as legislation to increase taxes on tobacco products or even more stringent restrictions on access.²⁵¹ In fact, lawmakers have proposed major tax increases on the sale of cigarettes, which would reduce sales (especially among youngsters) without infringing on constitutionally protected speech.²⁵²

The FDA originally had argued, among other things, that the government's greater power to ban tobacco products includes the lesser power to regulate extensively the advertising of these products,²⁵³ and that it has "greater leeway" to regulate "speech with regard to socially harmful activities."²⁵⁴ In its latest commercial speech decision, however, the Supreme Court soundly rejected these arguments.²⁵⁵ Recognizing the weaknesses of its initial defense, the Agency included in the final

First Amendment challenge to a city's prohibition on all cigarette billboard advertising justified as a way to reduce underage smoking), *vacated*, 116 S. Ct. 2575 (1996), *reinstated*, 1996 U.S. App. LEXIS 29462 (4th Cir. Nov. 13, 1996).

251. *See 44 Liquormart*, 116 S. Ct. at 1510 ("[H]igher [alcohol] prices can be maintained either by direct regulation or by increased taxation."); *id.* at 1522 (O'Connor, J., concurring in judgment).

252. *See* John Schmeltzer & Michael Arndt, *Under Siege in Cigarette Wars, Tobacco Titans Counterattack*, CHI. TRIB., Mar. 25, 1994, at 1. Commentators on the proposed tax increase note that, because minors have less disposable income than adults, there will be a greater reduction in overall tobacco consumption by minors. *See* David Bourne et al., *The Effect of Raising State and Federal Tobacco Tax*, 38 J. FAM. PRAC. 300 (1994); *see also* 60 Fed. Reg. 41,314, 41,324 (1995) ("Young people, who generally have little disposable income, can be particularly sensitive to the price of cigarettes and may choose not to smoke as the price increases."); *cf.* 61 Fed. Reg. at 44,453 ("The agency cannot act on these comments as it lacks the authority to levy taxes or mandate prices.").

253. *See* 60 Fed. Reg. at 41,355 (citing *Posadas de Puerto Rico Assocs. v. Tourism Co. of Puerto Rico*, 478 U.S. 328, 345-46 (1986)).

254. *Id.* (claiming that *Rubin v. Coors Brewing Co.*, 115 S. Ct. 1595 (1995), is not contrary).

255. *See 44 Liquormart*, 116 S. Ct. at 1511-13 ("The reasoning in *Posadas* does support the State's argument, but, on reflection, we are now persuaded that *Posadas* erroneously performed the First Amendment analysis," including its significant deference to a state legislature's choice of means, its "greater-includes-the-lesser" reasoning, and its supposed "vice" exception.); *id.* at 1513 ("As the entire Court apparently now agrees, the statements in the *Posadas* opinion on which Rhode Island relies are no longer persuasive."); *id.* at 1522 (O'Connor, J., concurring in judgment) ("The closer look that we have required since *Posadas* comports better with the purpose of the analysis set out in *Central Hudson* . . ."); *see also Coors*, 115 S. Ct. at 1589-91 n.2 (rejecting government's suggestion that it has "broader latitude to regulate speech that promotes socially harmful activities"); *City of Lakewood v. Plain Dealer Publishing Co.*, 486 U.S. 750, 763 (1988).

preamble a more sophisticated response to these constitutional objections.²⁵⁶ Although one may quibble with some of the advertising restrictions, a reviewing court will probably sustain their constitutionality on the strength of the evidentiary record amassed by the FDA in this case.

C. Special Concerns About Industry-Funded Counteradvertising

The proposed requirement that the tobacco industry spend \$150 million each year to broadcast anti-smoking messages poses additional First Amendment difficulties. The FDA, originally taking refuge in language from the statute's restricted device provisions, concluded that "an educational program about cigarettes and smokeless tobacco products is a restriction that is necessary because of the 'potentiality for harmful effect' of [tobacco] products."²⁵⁷ The Agency asserted that a national educational campaign is necessary to counteract the effects of the "appealing images" associated with smoking which have been perpetuated in the tobacco industry's advertising campaigns, and it summarized the evidence from independent studies to demonstrate the likely effectiveness of an industry-sponsored campaign.²⁵⁸ But a requirement that the tobacco industry en-

256. See 61 Fed. Reg. at 44,496-500.

257. See 60 Fed. Reg. at 41,350. Educational campaigns sometimes are mentioned as a possible alternative to a restriction on commercial speech, but courts assume a government-sponsored campaign and, in any event, can only speculate about its likely effectiveness. See, e.g., *44 Liquormart*, 116 S. Ct. at 1510 ("Even educational campaigns focused on the problems of . . . drinking might prove to be more effective."); see also *id.* at 1522 (O'Connor, J., concurring in judgment).

258. See 60 Fed. Reg. at 41,326-27; see also 61 Fed. Reg. at 44,538-39, 44,590; *supra* note 149 (describing the success of such programs in California and Massachusetts). Some critics believe that the approach could, however, prove to be counterproductive. See Carlo DiClemente, *Will the Regulations Work?*, HEALTH L. NEWS, Sept. 1995, at 6 (arguing that "societal efforts must avoid increasing attention to cigarettes, even if in a negative manner, or creating restrictions that would increase black market demand. Efforts to curb smoking . . . can have a reverse effect by creating a rebellious, recalcitrant cohort of smokers."); see also Robert S. Adler & R. David Pittle, *Cajolery or Command: Are Education Campaigns an Adequate Substitute for Regulation?*, 1 YALE J. ON REG. 159, 162-64 (1984); Lawrence O. Gostin & Allan M. Brandt, *Criteria for Evaluating a Ban on the Advertisement of Cigarettes: Balancing Public Health Benefits with Constitutional Burdens*, 269 JAMA 904, 906 (1993); Alan Schwartz, *Views of Addiction and the Duty to Warn*, 75 VA. L. REV. 509, 556-57 (1989).

gage in such counter-speech, ostensibly to correct misleading impressions from past promotional activities, contravenes the Constitution's special distrust of "forced" speech.

The First Amendment has been interpreted to include not only a right of free speech but also the right to refrain from speech which is abhorrent to the speaker.²⁵⁹ The Supreme Court has refused, for instance, to uphold orders requiring a corporation to associate itself with speech which the corporation may disagree with.²⁶⁰ The FDA's proposal was not just a limitation on labeling or advertising; instead, it would force the tobacco industry to speak. Rather than imposing a company-specific requirement or limitation to correct an identifiable past violation, the proposal sought to appropriate millions of dollars for an advertising campaign that would require industry endorsement of positions which the industry opposes. The First Amendment protects freedom of thought against state action, and this freedom includes both the right to speak freely and the right to refrain from speaking.²⁶¹

In defending its original proposal, the FDA never directly acknowledged this forced speech concern, although it cited decisions upholding "corrective" advertising orders imposed by other

259. See, e.g., *Abood v. Detroit Bd. of Educ.*, 431 U.S. 209, 235 (1977) (holding that employees could not be compelled to pay union dues); *Wooley v. Maynard*, 430 U.S. 705, 713 (1977) (holding that a state may not constitutionally require a motorist to display motto on license plate which conflicts with motorist's political, religious or moral beliefs); *Pacific Gas & Elec. Co. v. Public Utils. Comm'n*, 475 U.S. 1, 11-21 (1986) (holding that a public utilities commission could not, under the First Amendment, require a utility to include in its billing envelopes a third-party newsletter containing assertions regarding energy use with which the utility might disagree).

260. See *Pacific Gas*, 475 U.S. at 15-17 (noting that, "[w]ere the government freely able to compel corporate speakers to propound political messages with which they disagree, this [First Amendment] protection would be empty"); see also *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 72 (2d Cir. 1996) (granting preliminary injunctions against enforcement of state law requiring the disclosure of rBST use in the labeling of dairy products because "[t]he statute in question indisputably requires [manufacturers] to speak when they would rather not"); *Wileman Bros. & Elliott, Inc. v. Espy*, 58 F.3d 1367, 1380 (9th Cir. 1995) ("[A]lthough we agree that the Secretary [of Agriculture] has a substantial interest in promoting peaches and nectarines, we hold that forced contributions to pay for generic advertising programs contravene the First Amendment rights of the handlers."), *cert. granted*, 116 S. Ct. 1875 (1996).

261. See, e.g., *McIntyre v. Ohio Elections Comm'n*, 115 S. Ct. 1511, 1519-22 (1995); *Riley v. National Fed'n of the Blind*, 487 U.S. 781, 795-98 (1988); *Miami Herald Publ'g Co. v. Tornillo*, 418 U.S. 241, 256-57 (1974).

agencies.²⁶² Although courts have upheld limited corrective advertising orders in the past,²⁶³ the Agency's proposed plan far exceeds a traditional FTC cease and desist requirement.²⁶⁴ No agency has ever successfully mandated corrective advertising on an industry-wide basis. The FDA pointed to an educational requirement for hearing aids as an example of a previous company-financed educational message,²⁶⁵ but hearing aid manufacturers must distribute to purchasers only an informative brochure with their products,²⁶⁶ a requirement that differs little from typical labeling regulations.²⁶⁷ By comparison, an educational campaign cannot possibly target only potential adolescent users of a particular company's tobacco products.

V. CONCLUSION

The FDA's goal of substantially reducing the rate of tobacco use among adolescents is laudable, but the Agency has failed to

262. See 60 Fed. Reg. at 41,356. Although the final regulations do not include this requirement, the Agency explained that it would use its "notification" authority to order companies to undertake some counteradvertising. See 61 Fed. Reg. at 44,538 ("Because the education campaign will not be a requirement of this final rule, the agency need not respond to the many comments that it received . . ."). The FDA nevertheless briefly responded to some of the comments, though not with regard to the constitutional issues.

263. See, e.g., National Comm'n on Egg Nutrition v. FTC, 570 F.2d 157, 164 (7th Cir. 1977) (modifying overbroad corrective advertising order); cf. Warner-Lambert Co. v. FTC, 562 F.2d 749, 762 (D.C. Cir. 1977) (upholding FTC corrective advertising order where a manufacturer had made false and misleading statements about the efficacy of its mouthwash product, Listerine, in the prevention, cure, treatment, and mitigation of colds and severe sore throats).

264. The FDA's broad rulemaking approach differs significantly from the FTC's case-by-case adjudication of misleading advertising claims. See Richard S. Higgins & Fred S. McChesney, *Truth and Consequences: The Federal Trade Commission's Ad Substantiation Program*, in PUBLIC CHOICE AND REGULATION: A VIEW FROM INSIDE THE FEDERAL TRADE COMMISSION 181, 182-84 (Robert J. Mackay et al. eds., 1987); Arthur Best, *Controlling False Advertising: A Comparative Study of Public Regulation, Industry Self-Policing, and Private Litigation*, 20 GA. L. REV. 1, 16-20 (1985).

265. See 60 Fed. Reg. at 41,351.

266. See 21 C.F.R. § 801.420(c)(3) (1996). The Agency argues that it is impossible to set up a regulatory scheme which would involve only the dissemination of limited, targeted information to those adolescents who are susceptible to taking up smoking and that, therefore, a nationwide campaign is necessary. See 60 Fed. Reg. at 41,351.

267. See Noah & Noah, *supra* note 247, at 105-07 (discussing possible constitutional objections to product warning label requirements).

appreciate (or admit) the limitations of its statutory authority and some of the other weaknesses of its regulations. The initiative still may succeed in prompting a more moderate legislative response to the problem. In the meantime, however, the FDA may have done itself irreparable harm and diverted valuable time and resources from matters that it clearly does have responsibility to control.